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The EU Legislation on GMOs

An overview

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The mission of the JRC-IHCP is to protect the interests and health of the consumer in the framework of EU legislation on chemicals, food, and consumer products by providing scientific and technical support including risk-benefit assessment and analysis of traceability.

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INTRODUCTION

Genetic modification, also known as "genetic engineering" or "recombinant-DNA technology" was first applied in the 1970's. As an application of modern biotechnology, this technique allows selected individual genes to be transferred from one organism into another, also between non-related species. It is therefore one of the methods to introduce novel traits or characteristics into micro-organisms, plants and animals. The products obtained from this technology are commonly called "Genetically Modified Organisms (GMOs).

Genetically modified organisms (GMOs) are officially defined in the EU legislation as "organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination".

The most common types of GMOs that have been developed and commercialised so far are genetically modified crop plant species, such as genetically modified maize, soybean, oilseed rape and cotton varieties. Such varieties have mainly been genetically modified to provide resistance to certain insect pests and/or tolerance to herbicides.

The application of this technology is strictly regulated and the European Union has established an extensive legal framework on GMOs since the early 1990s.

EU legislation on GMOs has two main objectives:

- To protect health and the environment : a genetically modified organism (GMO) or a food product derived from a GMO can only be put on the market in the EU after it has been authorised on the basis of a detailed EU procedure based on a scientific assessment of the risks to health and the environment.

- To ensure the free movement of safe and healthy genetically modified products in the European Union: once authorised on the basis of the strict EU GMO authorisation procedure, genetically modified products can be placed on the whole EU market.

The entire corpus of European GMO legislation has been amended between 2000 and 2003, leading to the creation of a whole updated EU legal framework on GMOs as of 2003.

Within this extensive EU legislation on GMOs, the two main legal instruments are:

1. **Directive 2001/18/EC on the deliberate release into the environment of Genetically Modified Organisms**

Directive 2001/18/EC outlines the principles for, and regulates the deliberate release of GMOs into the environment in the EU.

The key objective of Directive 2001/18/EC is to protect human health and the environment in relation to GMO release into the environment. It covers two types of GMO activities:

- The experimental release of GMOs into the environment (for example the cultivation of GMOs in connection with experimental field tests), which is regulated by Part B of the Directive.

- The placing on the market of GMOs (for example the commercial cultivation of GM seeds in the EU, the importation and transformation of GM grains in the EU), which is regulated by Part C of the Directive.

Note: Directive 2001/18/EC has replaced the first EU Directive on GMOs, Directive 90/220/EEC, adopted in 1990.

2. Regulation (EC) No 1829/2003 on genetically modified food and feed

Regulation (EC) No 1829/2003 outlines the principles for, and regulates the placing on the market of food and feed consisting of, containing or produced from GMOs (referred to as genetically modified food and feed). It provides the general framework for regulating GM food and feed in the EU.

Key objectives of Regulation (EC) No 1829/2003 are:

- To protect human and animal health by introducing at EU level a safety assessment of the highest possible standards, before any GM food and feed is placed on the market.

- To have in place harmonised procedures for risk assessment and authorisation of GM food and feed that are efficient, time-limited and transparent.

- To ensure clear labelling of GM food and feed in order to respond to consumers' concerns and enable them to make an informed choice.

The present report provides an overview of the key provisions of the extensive EU legislation on GMOs (as of December 2011).

RELEASE OF GMOS INTO THE ENVIRONMENT

Directive 2001/18/EC (OJ L106 of 17.04.2001) on the "deliberate release of GMOs into the environment" regulates the releases of GMOs into the environment, be it for experimental purposes (field trials) or for commercial purposes (placing on the market).

Directive 2001/18/EC provides for the Community procedure for granting consent for deliberate release of GMOs into the environment. Its key provisions include:

- The EU definition of a GMO (see article 2): a genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetically material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Annex IA part 1 lists techniques which are considered to result in genetic modification.
Annex IA part 2 lists techniques which are not considered to result in genetic modification.
Annex IB lists techniques of genetic modification which are excluded from the Directive.

- Common methodology and principles for environmental risk assessment (see Annex II) before any GMO release into the environment

- Mandatory labelling and traceability of GMOs at all stages of the placing on the market

- Mandatory post-market monitoring requirements, including on long-term effects associated with the interaction with other GMOs and the environment

- Approvals for the release of GMOs to be limited to a maximum of ten years (renewable)

- Mandatory information to the public, including public registers for recording information on deliberate release of GMOs into the environment

Authorisation procedure for experimental releases

To obtain this authorisation, the applicant (called "the notifier") must submit an application (called "the notification") containing the particulars set out in part B of Directive 2001/18/EC (see Article 6). These particulars must include an evaluation of the environmental risks which the notifier has carried out.

The decision to authorise (or reject) the release of the GMO is exclusively incumbent on the competent national authority which has received the notification. Hence the authorisation procedure for experimental release is a purely national one. This corresponds to a feature of the authorisation of release for experimental purposes. The authorisation to proceed with this release applies only in the Member State in which the notification has been submitted.

In the event of authorisation, the notifier may release the GMO in compliance with the conditions set out in this authorisation.

Public information about all experimental releases authorised by the various EU Member States (see Article 11) is available at **GMO Register**.

Authorisation procedure for commercial releases

As opposed to the release for experimental purposes, the authorisation procedure for placing a GMO on the market is not a national one, but is a Community one involving all EU Member States. This can be explained by the fact that the authorisation for placing on the market of a GMO implies the free movement of the authorised products throughout the territory of the European Union. Hence all EU Member States are concerned.

Application:
The application (called "notification") is first submitted to the competent national authority of one Member State (which will later issue the final written authorisation permitting the placing on the market of the product in question within the Community.) The notification must include the particulars listed in part C of Directive 2001/18/EC (see Article 13), in particular:

- Detailed information on the GMO (in line with Annexes III and IV, including amongst others, information which can be used for the detection and identification of particular GMO products – see Annex IV A.7)
- Environmental risk assessment (in line with Annex II)
- Proposed period of consent not exceeding ten years
- Post-market monitoring plan (in line with Annex VII)
- Proposal for labelling (in line with Annex IV), including the words "This product contains genetically modified organisms"
- Summary of the notification

National Safety Assessment:
Having received the notification, the national authority must issue an opinion which takes the form of an "assessment report". In the event of a favourable opinion for the placing on the market of the GMO concerned, the Member State, after having received the notification and produced the assessment report, informs the other Member States via the European Commission (see Article 14).

EU Safety Assessment:
The Commission asks then for the opinion of the European Food Safety Authority (EFSA), composed of independent scientists, highly qualified in the fields associated with medicine, nutrition, toxicology, biology, chemistry and other similar disciplines. The environmental risk assessment run by the EFSA GMO panel includes the following (see Annex II of Directive 2001/18/EC):
- Identification of any characteristics of the GMO(s) which may cause adverse effects
- Evaluation of the potential consequences of each adverse effect
- Evaluation of the likelihood of the occurrence of each identified potential adverse effect
- Estimation of the risk posed by each identified characteristic of the GMO(s)

- Application of management strategies for risks resulting from the deliberate release or placing on the market of GMO(s)
- Determination of the overall risk of the GMO(s)

EU Authorisation:
In case of a favourable opinion from the EFSA, the Commission then presents a draft decision to the Regulatory Committee composed of representatives of the Member States for an opinion.
If the Committee gives a favourable opinion by qualified majority, the Commission adopts the decision.
If not, the draft Decision is submitted to the Council of Ministers for adoption or rejection by qualified majority.
If the Council does not act within three months, the Commission shall adopt the decision.

The consent for placing on the market is given for a maximum of ten years and is renewable (see article 17).

The consent for placing on the market is valid throughout the Community however, according to the safeguard clause laid down in Article 23, a Member State may provisionally ban the placing on the market on its territory of an approved GMO. This provisional ban must be based on availability of new safety information and an EU decision must be taken on this ban in the same way as for the EU authorisation procedure (EFSA consultation and Member States vote).

During the authorisation process, the public is informed (see Article 24) and has access to publicly available data (like for example the summary notification formats (SNIFs) from the notifier, the assessment reports from the national competent authorities, the opinions of the European Food Safety Authority, the authorisation decisions of the European Commission).

Decision 2004/204/EC (OJ L 65 of 03.03.2004) details the arrangements for the operation of the registers recording information on GMOs, as provided for in article 31 of Directive 2001/18/EC.

These public GMO registers are available at **GMO Register**

FOOD AND FEED USE OF GMOS

Regulation (EC) No 1829/2003 on genetically modified food and feed (OJ L268 of 18.10.2003) regulates the placing on the EU market of the following products:

- Food containing, consisting of or produced from GMOs (genetically modified food)
- Feed containing, consisting of or produced from GMOs (genetically modified feed)

Note: the definition of a GMO is the one laid down in article 2 of Directive 2001/18/EC (an organism in which the genetically material has been altered in a way that does not occur naturally by mating and/or natural recombination).

Key objectives of Regulation (EC) No 1829/2003 are (see article 1):
- A high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market
- Community procedures for the authorisation and supervision of genetically modified food and feed
- Provisions for the labelling of genetically modified food and feed.

Consequently Regulation (EC) No 1829/2003 provides for the Community procedure for granting consent for the placing on the EU market of GM food and feed. Its key provisions include:

- The general requirement that a GMO food/feed cannot be placed on the EU market unless it is covered by an authorisation granted according to Regulation (EC) No 1829/2003.

- A single harmonised, efficient, time-limited and transparent EU procedure for all applications for placing on the market of GM food/feed (whether they concern the GMO itself or the food and feed products derived there from).
This means that operators may file a single application for the GMO and all its uses (including possibly cultivation), that a single risk assessment is performed and that a single authorisation is granted for a GMO and all its uses (cultivation and/or importation and/or processing into food/feed and/or industrial products), in line with the so-called "one door - one key" principle.

- The authorisation process is based on an independent Community risk assessment carried out by the European Food Safety Authority (EFSA)

- Mandatory GM labelling for GM food/feed, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product (while before 2003, EU regulatory requirements on GM labelling were based on the detection of DNA or protein resulting from the genetic modification).

- A labelling threshold of 0,9% to exempt from GM labelling the adventitious or technically unavoidable presence of GM material in food or feed

- Mandatory submission of detection methods and samples of GM food/feed, including validation by the European Union Reference Laboratory on GM Food and Feed

- Approvals for a GM food/feed to be limited to a maximum of ten years (renewable)

Authorisation procedure for GM food and feed

This authorisation, valid throughout the Community, is granted subject to a single risk assessment process under the responsibility of the European Food Safety Authority and a single risk management process involving the Commission and the Member States through the regulatory committee procedure.

Application:
The application for an authorisation for the placing on the market of a GM food/feed has to be sent to a competent authority at national level, which has to acknowledge the receipt of the application within 14 days and to inform EFSA without delay. The application must clearly define the scope of the application, indicate which parts are confidential and must include the particulars listed in articles 5 and 17, including amongst others:

- Copy of the safety studies carried out to demonstrate that the GM food/feed do not have adverse effects on human health, animal health or the environment
- Methods for detection, sampling and identification of the GM food/feed
- Samples of the GM food/feed and control samples
- A summary of the dossier

EU Safety Assessment:
The application and any supplementary information supplied by the applicant must be made available to EFSA, which is responsible for the scientific risk assessment covering both the environmental risk and human and animal health safety assessment (see articles 6 and 18). EFSA must give its opinion within 6 months of receiving the application. However, if additional data is requested during the scientific assessment the time limit is extended. The EFSA opinion is made available to the public, who has the opportunity to make comments.

Note: an overview of the GM food/feed applications received by EFSA and of the scientific opinions adopted by the GMO Panel of EFSA is available at **EFSA GMO Panel**.

Validation of the detection method submitted for the GM food/feed is an integral part of this assessment process since the validated detection method is to be included in the final EFSA opinion. Consequently a GM food/feed cannot be authorised in the EU before a relevant detection method has been validated. The method validation process is conducted by the European Commission's Joint Research Centre (JRC) in its capacity of European Union Reference Laboratory (EU-RL) for GM Food and Feed, assisted by the European Network of GMO Laboratories (ENGL) – see articles 32 and Annex of Regulation (EC) No 1829/2003.

Method validation reports are published on the JRC website at **EU-RL GMFF** (see further details in the chapter on "GMO detection")

EU authorisation:
Within 3 months of receiving the overall EFSA opinion, the European Commission submits a draft Decision for approval by qualified majority to the Standing Committee on the Food Chain and Animal Health, composed of representatives of the Member States (see articles 7 and 19).
If the Committee gives a favourable opinion, the Commission adopts the Decision.
If not, or in the event of rejection of the Commission's proposal by qualified majority of the Committee, the draft Decision is submitted to the Council of Ministers for adoption or rejection by qualified majority.
If the Council does not act within three months or does not obtain a qualified majority for the adoption or rejection of the Commission's proposal, the Commission shall adopt the decision.

Once granted, the GM food/feed authorisations are valid throughout the Community for 10 years and are renewable (see articles 11 and 23).

The authorised GM food/feed are subject to specific GM labelling requirements including the words 'genetically modified' (see articles 13 and 25).
See further details in the chapter on "Traceability and Labelling of GMOs"

The authorised GM food/feed are entered into a Community register of genetically modified food and feed (see article 28), which includes public information on the relevant products and which is available at **GM Food Feed Register**

On 15 July 2011 an important new **Regulation (EU) No 619/2011** (OJ L 166 of 25.06.2011) entered into force.

This regulation, the so-called Low Level Presence (LLP) regulation, lays down "the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired".

The key objectives of this regulation are to harmonise the implementation of the EU zero-tolerance policy on non-authorised genetically modified (GM) material in feed and to address EU business operator's legal uncertainty when marketing feed imported from non-EU countries.

The key points of this new Regulation are to:

- Set a technical zero at a level of 0.1 % - the lowest level of GM material considered by the EU Reference Laboratory for the validation of quantitative methods.

  In practice Member States will have to declare a product as non-compliant when, taking into account the margin of error in the results (measurement uncertainty), the level of 0.1% is exceeded.

- Harmonise sampling and testing controls in all EU countries

- Set the following compliance criteria for non-authorised GM material in feed:

  - be authorised for commercialisation in a non-EU country;
  - have a valid EFSA application under Article 17 of Regulation EC 1829/2003 or have an expired authorisation under Regulation EC 1829/2003;
  - this GMFF application must be pending for more than 3 months, together with the additional requirements:
    - have not been identified by EFSA as susceptible to have adverse effects on health or the environment when present under 0.1%;
    - quantitative method of analysis published by the EU reference laboratory;
    - certified reference material must be available to EU-countries and third parties;

TRACEABILITY AND LABELLING OF GMOS

Traceability

Products which consist of GMOs or which contain GMOs and food products derived from GMOs, which have been authorised under Directive 2001/18/EC (Part C) or under Regulation (EC) No 1829/2003, are subject to traceability requirements in application of **Regulation (EC) No 1830/2003** (OJ L 268 of 18.10.2003).

Traceability is defined as "the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market" (see article 3).

Mandatory traceability of GMOs as provided for by Regulation (EC) No 1830/2003 facilitates:
- Control and verification of labelling claims
- Targeted monitoring of potential effects on health and the environment, where appropriate
- Withdrawal of products that contain or consist of GMOs where an unforeseen risk to human health or the environment is established.

The traceability rules make it mandatory on the operators concerned, i.e. all persons who place a product on the market or receive a product placed on the market within the Community, to be able to identify their supplier and the companies to which the products have been supplied.

The traceability requirement varies depending on whether the product consists of or contains GMOs (Article 4) or has been produced from GMOs (Article 5).

(1) In the case of a product consisting of or containing GMOs:
Operators must ensure that the following information is transmitted in writing to the operator receiving the product:
- An indication that the product contains or consists of GMOs.
- The unique identifier(s) assigned to those GMOs

(2) In the case of products produced from GMOs:
Operators must ensure that the following information is transmitted in writing to the operator receiving the product:
- An indication of each of the food ingredients which is produced from GMOs.
- An indication of each of the feed materials which is produced from GMOs.

In both cases (products consisting of GMOs or products produced from GMOs), operators must hold the information for a period of five years from each transaction and be able to identify the operator by whom and to whom the products have been made available. In order to respect these traceability requirements, it is important that each operator has in place a system to allow the information to be kept and to make it available to the public authorities on demand.

Note: **Regulation (EC) No 65/2004** (OJ L 10 of 16.01.2004) details the system for the assignment and the format of Unique Identifiers for GMOs

Labelling

Besides traceability requirements, products consisting of or containing GMOs and food products produced from GMOs which are authorised under Directive 2001/18/EC (Part C) or under Regulation (EC) No 1829/2003 are subject to the mandatory GM labelling requirements laid down in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003.

Mandatory GM Labelling requirements aim to inform the consumer and user of the product, hence allowing them to make an informed choice.

Generally speaking, for all products consisting of or containing GMOs, Regulation (EC) No 1830/2003 requires that operators indicate on a label: “This product contains genetically modified organisms” or “This product contains genetically modified [(name of organism(s)]”.

Regulation (EC) No 1829/2003 lays down specific labelling requirements as regards genetically modified food and feed:

Genetically modified food must be labelled in accordance with Articles 12 and 13 of Regulation (EC) No 1829/2003 i.e. with the words "genetically modified" or "produced from genetically modified (name of the ingredient)", irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product. This is a change compared to previous EU legislation: before 2003 GM labelling requirements were based on the detection of DNA or protein resulting from the genetic modification. The new GM labelling requirement therefore also includes highly refined products, such as oil obtained from genetically modified soya or maize.

The same GM labelling rules apply to animal feed in compliance with Articles 24 and 25 of Regulation (EC) No 1829/2003, including any compound feed that contains or is produced from genetically modified soya or maize for instance, so as to provide livestock farmers with accurate information on the composition and properties of feed. This is also a change compared to previous EU legislation: before 2003 there were no GM labelling requirements for feed produced from GMOs.

Exemption from the traceability and labelling requirements

Conventional products, i.e. those produced without genetic modification, may unintentionally contain traces of GMOs, for example, due to cross-pollination during cultivation, or due to adventitious or technically unavoidable mix of GM and non-GM during harvesting, storage, and transport or processing. This does not only apply to GMOs since in the production of food, feed and seed, it is practically impossible to achieve products that are 100% pure.

Taking this into account, the legislation has laid down a 0.9% threshold to exempt from GMO traceability and labelling requirements conventional products containing unintentional traces of GMOs below 0.9%.

Articles 12 and 24 of Regulation (EC) No 1829/2003 (and articles 4 and 5 of Regulation (EC) No 1830/2003) provide that GMO traceability and labelling requirements do not apply to food and feed containing GM material in a proportion no higher than 0,9 per cent, provided that this presence is adventitious or technically unavoidable.

In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.

DETECTION OF GMOS

Submission and validation of GMO detection methods are an integral part of the EU regulatory approval process for GMOs since Regulation (EC) No 1829/2003 (articles 5 and 17) provides that the application for authorisation should include, amongst others:

- Methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it.

- Samples of the food and their control samples, and information as to the place where the reference material can be accessed. Control samples mean the GMO or its genetic material (positive sample) and the parental organism or its genetic material that has been used for the genetic modification (negative sample).

Article 32 of Regulation (EC) No 1829/2003 provides that the European Union Reference Laboratory for GM Food Feed and its duties are those referred in the Annex of Regulation (EC) No 1829/2003.

Article 32 of Regulation (EC) No 1829/2003 also stipulates that applicants for authorisation of GM food/feed should contribute to supporting the costs of the tasks of the European Union Reference Laboratory and the European Network of GMO Laboratories mentioned in the Annex.

The Annex of Regulation (EC) No 1829/2003 (as amended by Annex III of Regulation (EC) No 1981/2006) provides that:

1. The European Union Reference Laboratory referred to in Article 32 is the Commission's Joint Research Centre.

2. For the duties and tasks outlined in this Annex, the European Union Reference Laboratory shall be assisted by the national reference laboratories referred to in Article 32, which shall consequently be considered as members of the consortium referred to as the “European Network of GMO laboratories”.

3. The European Union Reference Laboratory shall be responsible, in particular, for:

(a) the reception, preparation, storage, maintenance and distribution to the members of the European Network of GMO laboratories of the appropriate positive and negative control samples, subject to assurance given by such members of the respect of the confidential nature of the data received where applicable;

(b) without prejudice to the responsibilities of the European Union Reference laboratories laid down in Article 32 of Regulation (EC) No 882/2004, the distribution to national reference laboratories within the meaning of Article 33 of that Regulation of the appropriate positive and negative control samples, subject to assurance given by such laboratories of the respect of the confidential nature of the data received where applicable;

(c) evaluating the data provided by the applicant for authorisation for placing the food or feed on the market, for the purpose of testing and validation of the method for sampling and detection;

(d) testing and validating the method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed;

(e) submitting full evaluation reports to the Authority.

4. The European Union Reference Laboratory shall play a role in dispute settlements concerning the results of the tasks outlined in this Annex, without prejudice to the responsibilities of the European Union Reference laboratories laid down in Article 32 of Regulation (EC) No 882/2004.

Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 provides further details on the applications for authorisation of GM food and feed, including the method(s) of detection, sampling and event specific identification of the transformation event, as provided for in articles 5(3) and 17(3) of Regulation (EC) No 1829/2003.

In particular Annex I of Regulation (EC) No 641/2004 on "method validation" provides detailed technical provisions on the type of information on detection methods that shall be provided by the applicant and that is needed to verify the preconditions for the fitness of the method. This includes information about the method as such and about the method testing carried out by the applicant.

Annex I of Regulation (EC) No 641/2004 also confirms that the validation process will be carried out by the EU-RL according to internationally accepted technical provisions. All guidance documents referred to in this Annex or produced by the European Union Reference Laboratory (EU-RL) are to be made available by the EU-RL.

Note: Annex II of Regulation (EC) No 641/2004 addresses in particular "reference material".

Regulation (EC) No 1981/2006 provides further detailed rules specific for the implementation of article 32 of Regulation (EC) No 1829/2003 on the European Union Reference for Genetically Modified Organisms, in particular about:

- The contribution to the costs of the tasks of the EU-RL and of the national reference laboratories

- The establishment of national reference laboratories assisting the EU-RL for testing and validating the methods of detection and identification.

Annex I of Regulation (EC) No 1981/2006 lays down the minimum requirements to be fulfilled by the National Reference Laboratories assisting the EU-RL (including to be accredited, or being in the process of accreditation according to EN ISO/IEC 17025).

Annex II of Regulation (EC) No 1981/2006 lists the laboratories appointed as "national reference laboratories" under Regulation (EC) No 1829/2003 to assist the EU-RL for testing and validating detection methods.

Annex III of Regulation (EC) No 1981/2006 amends the Annex of Regulation (EC) No 1829/2003.

Note: **Commission Recommendation 2004/787/EC** (OJ L 348 of 24.11.2004) also provides technical guidance for sampling and detection of GMOs, in particular about sampling protocols and analytical test protocols.

Based on Regulation (EC) No 1829/2003, the European Union Reference Laboratory for GM food/feed (EU-RL-GMFF) is therefore validating each individual event-specific detection method to provide control laboratories with appropriate analytical tools. These methods are validated according to international standards and only methods fully meeting validation criteria are fit for regulatory purposes.

Detailed information on the activities of the European Union Reference Laboratory for GM food/feed (incl. list and protocols of validated detection methods) is available on the **EU-RL GMFF** website. Since May 2011 a searchable **EU Database of Reference Methods for GMO Analysis** is also available on the EU-RL GMFF website.

In addition to the tasks of the EU-RL provided for in Regulation (EC) No 1829/2003 concerning the validation of methods for the GM food/feed authorisation procedure, the EU-RL has additional responsibilities under **Regulation (EC) No 882/2004** on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Regulation (EC) No 882/2004 lays down general rules for the performance of official controls i.e. any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules. In particular, Title III of Regulation (EC) No 882/2004 deals with the responsibilities of "reference laboratories" (including European Union Reference Laboratories EU-RL - see article 32 and National Reference Laboratories NRL - see article 33).

Annex VII of Regulation (EC) No 882/2004 lists the various European Union Reference Laboratories for Food and feed and provides in particular that the European Union Reference Laboratory for genetically modified organisms (GMOs) is the same laboratory as referred to in the Annex of Regulation (EC) No 1829/2003 on GM food/feed (i.e. the Commission Joint Research Centre).

Pursuant to Article 32 of Regulation (EC) No 882/2004, all European Union Reference Laboratories (EU-RLs) for feed and food referred to in Annex VII (including therefore the European Union Reference Laboratory for genetically modified organisms) are responsible for:

(a) providing national reference laboratories with details of analytical methods, including reference methods;

(b) coordinating application by the national reference laboratories of the methods referred to in (a), in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;

(c) coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;

(d) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;

(e) providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;

(f) collaborating with laboratories responsible for analysing feed and food in third countries.

Pursuant to Article 33 of Regulation (EC) No 882/2004, the Member States should designate one or more National Reference Laboratories (NRLs) for each EU-RL referred to in article 32 (including therefore the European Union Reference Laboratory for genetically modified organisms). The responsibilities of these NRLs are to:

(a) collaborate with the European Union Reference Laboratory in their area of competence;

(b) coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Article 11;

(c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;

(d) ensure the dissemination to the competent authority and official national laboratories of information that the European Union Reference Laboratory supplies;

(e) provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53;

(f) be responsible for carrying out other specific duties provided for in accordance with the procedure referred to in Article 62(3), without prejudice to existing additional national duties.

Note: a list of the various NRLs responsible for GMO controls is available at **GMO NRLs**

COEXISTENCE

The cultivation of GMOs in the EU has implications for the organisation of agricultural production. On the one hand, the possibility of the unintended presence of GM crops in non-GM crops (conventional and organic), raises the question as to how producer choice for the different production types can be ensured. In principle, farmers should be able to cultivate the types of agricultural crops they choose - be it GM crops, conventional or organic crops. This possibility should be combined with the wish of some farmers and operators to ensure that their crops have the lowest possible presence of GMOs.

The objective of co-existence measures in areas where GMOs are cultivated is to avoid unintended presence of GMOs in other products, preventing the potential economic loss and impact of the admixture of GM and non-GM crops (including organic crops).

Note: coexistence always refers to GMOs that have passed the very strict EU authorisation process, including comprehensive assessments of health-related or environmental risks. Therefore, coexistence measures should not concern environmental or health-related risks (management of environmental or health-related risks is addressed during the GMO authorisation process). Coexistence measures should concern "only" economic risks (i.e. the potential economic loss and impact of the admixture of GM and non-GM crops).

In March 2003, the Commission agreed that it should be up to the Member States to develop and implement management measures concerning coexistence, in accordance with the subsidiarity principle. Consequently no EU legislation on coexistence has been developed.

In order to help the Member States in developing national approaches to co-existence, the Commission adopted in July 2003 Recommendation 2003/556/EC (OJ L189 of 29.07.2003) on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming.

Experience gained over the years showed that Member States need more flexibility to take into consideration their particular local, regional and national conditions when defining measures to organise the cultivation of GM, conventional and organic crops.

The first Recommendation 2003/556/EC was therefore replaced in July 2010 by a new **Commission Recommendation 2010/C200/01** on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops.

Commission Recommendation 2010/C200/01 states in particular that:

- The present guidelines take the form of non-binding recommendations addressed to the Member States. They are intended to provide general principles for the development of national measures to avoid the unintended presence of GMOs in conventional and organic crops. It is recognised that many of the factors that are important in this context are specific to national, regional and local conditions.

- The adventitious presence of GMOs above the tolerance threshold set out in EU legislation triggers the need for a crop that was intended to be a non-GMO crop, to be labelled as containing GMOs. This could cause a loss of income, due to a lower market price of the GM crop or difficulties in selling it. Moreover, additional costs might incur to farmers if they have to adopt monitoring systems and measures to minimise the admixture of GM and non-GM crops.

- However, the potential loss of income for producers of particular agriculture products such as organic products is not necessarily limited to exceeding the labelling threshold set out in EU legislation at 0,9%. In certain cases, and depending on market demand and on the respective provisions of national legislations (e.g. some Member States have developed national standards for different types of ‘GM-free’ labelling), the presence of traces of GMOs in particular food crops - even

at a level below 0,9% - may cause economic damages to operators who would wish to market them as non-containing GMOs.

- The ongoing coordination through COEX-NET and technical advice by the European Coexistence Bureau (ECoB) will continue. ECoB will keep up to date an indicative catalogue of measures as well as a list of agronomic, natural and crop-specific factors to be considered when developing national measures to avoid the unintended presence of GMOs in conventional and organic crops. Member States should continue to contribute to the technical work of ECoB.

Note on the European Coexistence Bureau (ECoB):

The Commission has set up the European Coexistence Bureau (ECoB), located at the Institute for Prospective Technological Studies (IPTS) of the Commission's Joint Research Centre. The purpose of the European Coexistence Bureau (see **ECoB**) is to develop technical reference documents for best practices to achieve coexistence. The reference documents are to be elaborated in Technical Working Groups composed of national experts, and to provide Member States with non-binding guidelines for technical coexistence measures. The work will proceed on a crop-by-crop basis, with the first Technical Working Group developing a reference document for maize crop cultivation. ECoB started its work in 2008.

THE INTERNATIONAL ENVIRONMENT

The European Community is a party to the Cartagena Protocol on Biosafety (see Decision 2002/628/EC OJ L 201 31.07.2002 on conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety), which is annexed to the UNEP Convention on Biological Diversity and which entered into force on 11 September 2003.

The overall purpose of this United Nations agreement is to establish common rules to be followed in transboundary movements of GMOs in order to ensure, on a global scale, the protection of biodiversity and of human health.

The Cartagena Protocol on Biosafety includes provisions on a Biosafety Clearing-House (BCH), a central database which key role is the provision and exchange of information in support of implementation of the Protocol, in particular information related to:

- Competent national authorities on GMOs
- National legislation on GMOs
- Regulatory decisions on GMOs (approvals/prohibition) incl. summaries of risk assessments

National focal points for the Biosafety Clearing-House have been nominated by the Parties to the Protocol in order to liaise with the Convention Secretariat regarding issues of relevance to the development and implementation of the BCH. For the European Community, the focal point for the Biosafety Clearing-House is the Commission Joint Research Centre.

For further information on:
- The Cartagena Protocol on Biosafety see **Biosafety Protocol**
- The Biosafety Clearing House see **BCH**

The EU legislative framework on GMOs in place since 2003 takes account of the EU international trade commitments and of the requirements of the Cartagena Protocol on Biosafety, specifically as regards the obligations on importers of products in the EU and the obligations on exporters of products from the EU to third countries.

The incorporation of the Cartagena Protocol on Biosafety into EU legislation relies on a wide range of legislation governing the use of GMOs within the EU (see before).

A cornerstone of this legal framework is Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, which in particular addresses the regulation of imports of GMOs into the EU.

It is supplemented by **Regulation (EC) No 1946/2003** on the transboundary movements of GMOs (OJ L 287 of 05.11.2003) which in particular addresses the regulation of exports of GMOs from the EU. The main features of Regulation (EC) No 1946/2003 are:

- The obligation to notify exports of GMOs intended for deliberate release into the environment and to secure express consent prior to a first transboundary movement.
- The obligation to provide information to the public and to international partners on EU practices, legislation and decisions on GMOs.
- A set of rules for the export of GMOs intended to be used as food, feed or for processing.
- The information to be provided to the Biosafety Clearing House (BCH) on behalf of the Community.

ANNEXES

KEY EU REGULATORY TEXTS – LIST (1/2)

NUMBER	TOPIC	PUBLICATION	KEY PROVISIONS
Directive 2001/18/EC	Deliberate release into the environment of GMOs	OJ L 106 17.04.2001	Community procedure for authorisation of deliberate release (experimental or commercial) of GMOs into the environment Definition of a GMO Mandatory labelling of GMOs Registers for recording public information on GMOs
Regulation (EC) No 1829/2003	Genetically Modified Food and Feed	OJ L 268 18.10.2003	Community procedure for authorisation of both GM food and GM feed (including one door-one key authorisation process, allowing approval of a GMO under Regulation (EC) No 1829/2003 both for food/feed uses and for cultivation) Mandatory labelling of GM food and feed, irrespective of detectability of DNA or protein resulting from the genetic modification 0,9% labelling threshold for the adventitious or technically unavoidable presence of GM material in food or feed Mandatory submission of detection methods and samples of GM food/feed, including validation by the European Union Reference Laboratory (EU-RL)
Regulation (EC) No 1830/2003	Traceability and Labelling of GMOs and food feed produced from GMOs	OJ L 268 18.10.2003	Operators must transmit the following information to the operator receiving the product: - an indication that the product contains GMOs - the unique identifier(s) assigned to those GMOs
Regulation (EC) No 65/2004	System for assignment of Unique Identifiers for GMOs	OJ L 10 16.01.2004	Unique Identifiers should be assigned to GMOs according to the format defined in the Annex and should appear in the GMO authorisation
Regulation (EU) No 619/2011	Low Level Presence of GM material in feed	OJ L 166 25.06.2011	Harmonise the implementation of the EU zero-tolerance policy on non-authorised genetically modified (GM) material in feed by setting a technical zero at a level of 0.1 %

KEY EU REGULATORY TEXTS – LIST (2/2)

NUMBER	TOPIC	PUBLICATION	KEY PROVISIONS
Regulation (EC) No 641/2004	Detailed rules for implementation of Regulation (EC) No 1829/2003 on GM food feed	OJ L 102 07.04.2004	Details regarding the contents of an application for GM food feed authorisation, in particular regarding method validation and reference material
Regulation (EC) No 1981/2006	Detailed rules for implementation of article 32 of Regulation (EC) No 1829/2003 on the EU-RL for GMOs	OJ L 368 23.12.2006	Detailed rules concerning: - the contribution to the costs of the tasks of the European Union Reference Laboratory and of the National Reference Laboratories - the establishment of National Reference Laboratories assisting the EU-RL for GMOs
Recommendation 2004/787/EC	Technical guidance for sampling and detection of GMOs	OJ L 348 24.11.2004	Technical guidance in particular about sampling protocols and analytical test protocols
Regulation (EC) No 882/2004	Official controls performed to ensure compliance with feed and food law	OJ L165 30.04.2004 (corrigendum in OJ L 191 28.05.2004)	Community harmonised framework on official controls performed to ensure compliance with feed and food law Designation and activities of European Union Reference Laboratories and National Reference Laboratories (incl. on GMOs)
Regulation (EC) No 1946/2003	Transboundary Movement of GMOs	OJ L 287 05.11.2003	Specific requirements for exports of GMOs from the EU to third countries in order to ensure compliance with the obligations in the Cartagena Protocol on Biosafety (including information to be provided to third countries and to the Biosafety Clearing House BCH)

OTHER RELEVANT EU REGULATORY TEXTS - LIST

NUMBER	TOPIC	PUBLICATION
Decision 2004/204/EC	Detailed arrangements for the registers recording information on GMOs according to Directive 2001/18/EC	OJ L 65 03.03.2004
Recommendation 2010/01/EC	Guidelines for the development of national coexistence measures to avoid the unintended presence of GMOs in conventional and organic crops	OJ C 200 22.07.2010
Decision 2002/628/EC	Conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety	OJ L 201 31.07.2002
Directive 2009/41/EC	Contained use of Genetically Modified Micro-organisms	OJ L 125 21.05.2009
Directive 98/95/EC	Amendment of EU Seeds Directives in respect of GM varieties	OJ L 25 01.02.1999
Directive 2002/53/EC	Common Catalogue of plant varieties (incl. GM)	OJ L 193 20.07.2002
Decision 1999/468/EC	Procedures for implementing powers conferred on the Commission (incl. regulatory procedure)	OJ L 184 17.07.1999
Directive 2008/27/EC	Technical amendment to Directive 2001/18/EC as regards the implementing powers conferred on the Commission	OJ L 81 20.03.2008
Regulation (EC) No 298/2008	Technical amendment to Regulation (EC) No 1829/2003 as regards the implementing powers conferred on the Commission	OJ L 97 09.04.2008
Regulation (EC) No 834/2007	Organic production and labelling of organic products	OJ L 189 20.07.2007
Regulation (EC) No 1754/2006	Rules for financial assistance to European Union Reference Laboratories	OJ L 331 29.11.2006
Regulation (EC) No 178/2002	General Principles and requirements of Food Law, establishment of the European Food Safety Authority	OJ L 31 01.02.2002
Regulation (EC) No 258/97	Novel Foods (not including anymore GM foods since adoption of Regulation (EC) No 1829/2003)	OJ L 43 14.02.1997

ANNEXES

COPY OF KEY EU REGULATORY TEXTS ON GMOS

(in chronological order of publication)

1. **Directive 2001/18/EC** (Deliberate release into the environment of GMOs)
2. **Regulation (EC) No 1829/2003** (Genetically Modified Food and Feed)
3. **Regulation (EC) No 1830/2003** (Traceability and Labelling of GMOs)
4. **Regulation (EC) No 1946/2003** (Transboundary Movement of GMOs)
5. **Regulation (EC) No 65/2004** (Unique Identifiers for GMOs)
6. **Regulation (EC) No 641/2004** (Implementation of Regulation (EC) No 1829/2003)
7. **Regulation (EC) No 882/2004** (Official controls for feed and food law)
8. **Recommendation 2004/787/EC** (Guidance for sampling and detection of GMOs)
9. **Regulation (EC) No 1981/2006** (Implementation of Article 32 of Regulation (EC) No 1829/2003)
10. **Regulation (EU) No 619/2011** (Low Level Presence of GM material in feed)

ANNEX 1

I

(Acts whose publication is obligatory)

DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 March 2001

on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission ([1]),

Having regard to the opinion of the Economic and Social Committee ([2]),

Acting in accordance with the procedure laid down in Article 251 of the Treaty, in the light of the joint text approved by the Conciliation Committee on 20 December 2000 ([3]),

Whereas:

(1) The Report of the Commission on the Review of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms ([4]), adopted on 10 December 1996, identified a number of areas where improvement is needed.

(2) There is a need for clarification of the scope of Directive 90/220/EEC and of the definitions therein.

(3) Directive 90/220/EEC has been amended. Now that new amendments are being made to the Directive, it is desirable, for reasons of clarity and rationalisation, that the provisions in question should be recast.

(4) Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States. The effects of such releases on the environment may be irreversible.

(5) The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMOs).

(6) Under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken.

(7) It is necessary to approximate the laws of the Member States concerning the deliberate release into the environment of GMOs and to ensure the safe development of industrial products utilising GMOs.

(8) The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it.

(9) Respect for ethical principles recognised in a Member State is particularly important. Member States may take into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products.

(10) For a comprehensive and transparent legislative framework, it is necessary to ensure that the public is consulted by either the Commission or the Member States during the preparation of measures and that they are informed of the measures taken during the implementation of this Directive.

(11) Placing on the market also covers import. Products containing and/or consisting of GMOs covered by this Directive cannot be imported into the Community if they do not comply with its provisions.

(12) Making GMOs available to be imported or handled in bulk quantities, such as agricultural commodities, should be regarded as placing on the market for the purpose of this Directive.

(13) The content of this Directive duly takes into account international experience in this field and international

([1]) OJ C 139, 4.5.1998, p. 1.
([2]) OJ C 407, 28.12.1998, p. 1.
([3]) Opinion of the European Parliament of 11 February 1999 (OJ C 150, 28.5.1999, p. 363), Council Common Position of 9 December 1999 (OJ C 64, 6.3.2000, p. 1) and Decision of the European Parliament of 12 April 2000 (OJ C 40, 7.2.2001, p. 123). Decision of the European Parliament of 14 February 2001 and Decision of the Council of 15 February 2001.
([4]) OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

trade commitments and should respect the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. As soon as possible, and in any case before July 2001, the Commission should, in the context of the ratification of the Protocol, submit the appropriate proposals for its implementation.

(14) Guidance on the implementation of provisions related to the definition of the placing on the market in this Directive should be provided by the Regulatory Committee.

(15) When defining 'genetically modified organism' for the purpose of this Directive, human beings should not be considered as organisms.

(16) The provisions of this Directive should be without prejudice to national legislation in the field of environmental liability, while Community legislation in this field needs to be complemented by rules covering liability for different types of environmental damage in all areas of the European Union. To this end the Commission has undertaken to bring forward a legislative proposal on environmental liability before the end of 2001, which will also cover damage from GMOs.

(17) This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record.

(18) It is necessary to establish harmonised procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment.

(19) A case-by-case environmental risk assessment should always be carried out prior to a release. It should also take due account of potential cumulative long-term effects associated with the interaction with other GMOs and the environment.

(20) It is necessary to establish a common methodology to carry out the environmental risk assessment based on independent scientific advice. It is also necessary to establish common objectives for the monitoring of GMOs after their deliberate release or placing on the market as or in products. Monitoring of potential cumulative long-term effects should be considered as a compulsory part of the monitoring plan.

(21) Member States and the Commission should ensure that systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted. The necessary resources should be secured for such research by Member States and the Community in accordance with their budgetary procedures and independent researchers should be given access to all relevant material, while respecting intellectual property rights.

(22) The issue of antibiotic-resistance genes should be taken into particular consideration when conducting the risk assessment of GMOs containing such genes.

(23) The deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from, or containing GMOs.

(24) The introduction of GMOs into the environment should be carried out according to the 'step by step' principle. This means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken.

(25) No GMOs, as or in products, intended for deliberate release are to be considered for placing on the market without first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by their use.

(26) The implementation of this Directive should be carried out in close liaison with the implementation of other relevant instruments such as Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1]. In this context the competent authorities concerned with the implementation of this Directive and of those instruments, within the Commission and at national level, should coordinate their action as far as possible.

(27) Concerning the environmental risk assessment for part C, risk management, labelling, monitoring, information to the public and safeguard clause, this Directive should be a point of reference for GMOs as or in products authorised by other Community legislation which should therefore provide for a specific environmental risk assessment, to be carried out in accordance with the principles set out in Annex II and on the basis of information specified in Annex III without prejudice to additional requirements laid down by the Community legislation mentioned above, and for requirements as regards risk management, labelling, monitoring as appropriate, information to the public and safeguard clause at least equivalent to that laid down in this Directive. To this end it is necessary to provide for cooperation with the Community and Member State bodies mentioned in this Directive for the purpose of its implementation.

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 1999/80/EC (OJ L 210, 10.8.1999, p. 13).

(28) It is necessary to establish a Community authorisation procedure for the placing on the market of GMOs, as or in products, where the intended use of the product involves the deliberate release of the organism(s) into the environment.

(29) The Commission is invited to conduct a study which should contain an assessment of various options to improve further the consistency and efficiency of this framework, particularly focusing on a centralised authorisation procedure for the placing on the market of GMOs within the Community.

(30) For sectoral legislation, monitoring requirements may have to be adapted to the product concerned.

(31) Part C of this Directive does not apply to products covered by Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products ([1]), provided that it includes an environmental risk assessment equivalent to that provided for by this Directive.

(32) Any person, before undertaking a deliberate release into the environment of a GMO, or the placing on the market of GMOs, as or in products, where the intended use of the product involves its deliberate release into the environment, is to submit a notification to the national competent authority.

(33) That notification should contain a technical dossier of information including a full environmental risk assessment, appropriate safety and emergency response, and, in the case of products, precise instructions and conditions for use, and proposed labelling and packaging.

(34) After notification, no deliberate release of GMOs should be carried out unless the consent of the competent authority has been obtained.

(35) A notifier should be able to withdraw his dossier at any stage of the administrative procedures laid down in this Directive. The administrative procedure should come to an end when a dossier is withdrawn.

(36) Rejection of a notification for the placing on the market of a GMO as or in products by a competent authority should be without prejudice to the submission of a notification of the same GMO to another competent authority.

(37) An agreement should be reached at the end of the mediation period when no objections remain.

(38) Rejection of a notification following a confirmed negative assessment report should be without prejudice to future decisions based on the notification of the same GMO to another competent authority.

(39) In the interests of the smooth functioning of this Directive, Member States should be able to avail themselves of the various provisions for the exchange of information and experience before having recourse to the safeguard clause in this Directive.

(40) In order to ensure that the presence of GMOs in products containing, or consisting of, genetically modified organisms is appropriately identified, the words 'This product contains genetically modified organisms' should appear clearly either on a label or in an accompanying document.

(41) A system should be designed using the appropriate committee procedure, for the assignment of a unique identifier to GMOs, taking into account relevant developments in international fora.

(42) It is necessary to ensure traceability at all stages of the placing on the market of GMOs as or in products authorised under part C of this Directive.

(43) It is necessary to introduce into this Directive an obligation to implement a monitoring plan in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market.

(44) Member States should be able, in accordance with the Treaty, to take further measures for monitoring and inspection, for example by official services, of the GMOs as or in products placed on the market.

(45) Means should be sought for providing possibilities for facilitating the control of GMOs or their retrieval in the event of severe risk.

(46) Comments by the public should be taken into consideration in the drafts of measures submitted to the Regulatory Committee.

(47) The competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment.

(48) The administrative procedure for granting consents for the placing on the market of GMOs as or in products should be made more efficient and more transparent and first-time consent should be granted for a fixed period.

(49) For products for which consent has been granted for a fixed period a streamlined procedure should apply as regards the renewal of consent.

([1]) OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

(50) The existing consents granted under Directive 90/220/EEC have to be renewed in order to avoid disparities between consents granted under that Directive and those pursuant to this Directive and in order to take full account of the conditions of consent under this Directive.

(51) Such renewal requires a transitional period during which existing consents granted under Directive 90/220/EEC remain unaffected.

(52) When a consent is renewed, it should be possible to revise all the conditions of the original consent, including those related to monitoring and the time limitation of the consent.

(53) Provision should be made for consultation of the relevant Scientific Committee(s) established by Commission Decision 97/579/EC ([1]) on matters which are likely to have an impact on human health and/or the environment.

(54) The system of exchange of information contained in notifications, established under Directive 90/220/EEC, has been useful and should be continued.

(55) It is important to follow closely the development and use of GMOs.

(56) When a product containing a GMO, as or in products, is placed on the market, and where such a product has been properly authorised under this Directive, a Member State may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive. A safeguard procedure should be provided in case of risk to human health or the environment.

(57) The Commission's European Group on Ethics in Science and New Technologies should be consulted with a view to obtaining advice on ethical issues of a general nature regarding the deliberate release or placing on the market of GMOs. Such consultations should be without prejudice to the competence of Member States as regards ethical issues.

(58) Member States should be able to consult any committee they have established with a view to obtaining advice on the ethical implications of biotechnology.

(59) The measures necessary for the implementation of this Directive are to be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([2]).

(60) The information exchange set up under this Directive should also cover experience gained with the consideration of ethical aspects.

(61) In order to increase the effective implementation of the provisions adopted under this Directive it is appropriate to provide for penalties to be applied by Member States, including in the event of release or placing on the market contrary to the provisions of this Directive, particularly as a result of negligence.

(62) A report to be issued every three years by the Commission, taking into account the information provided by Member States, should contain a separate chapter regarding the socioeconomic advantages and disadvantages of each category of GMOs authorised for placing on the market, which will take due account of the interest of farmers and consumers.

(63) The regulatory framework for biotechnology should be reviewed so as to identify the feasibility of improving further the consistency and efficiency of that framework. Procedures may need to be adapted so as to optimise efficiency, and all options which might achieve that should be considered,

HAVE ADOPTED THIS DIRECTIVE:

PART A

GENERAL PROVISIONS

Article 1

Objective

In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when:

— carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,

— placing on the market genetically modified organisms as or in products within the Community.

Article 2

Definitions

For the purposes of this Directive:

(1) 'organism' means any biological entity capable of replication or of transferring genetic material;

(2) 'genetically modified organism (GMO)' means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

([1]) OJ L 237, 28.8.1997, p. 18.
([2]) OJ L 184, 17.7.1999, p. 23.

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

(3) 'deliberate release' means any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment;

(4) 'placing on the market' means making available to third parties, whether in return for payment or free of charge;

The following operations shall not be regarded as placing on the market:

— making available genetically modified microorganisms for activities regulated under Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms [1] including culture collections,

— making available GMOs other than microorganisms referred to in the first indent, to be used exclusively for activities where appropriate stringent containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment, the measures should be based on the same principles of containment as laid down in Directive 90/219/EEC,

— making available GMOs to be used exclusively for deliberate releases complying with the requirements laid down in part B of this Directive;

(5) 'notification' means the submission of the information required under this Directive to the competent authority of a Member State;

(6) 'notifier' means the person submitting the notification;

(7) 'product' means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market;

(8) 'environmental risk assessment' means the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose and carried out in accordance with Annex II.

[1] OJ L 117, 8.5.1990, p. 1. Directive as amended by Directive 98/81/EC (OJ L 330 5.12.1998, p. 13).

Article 3

Exemptions

1. This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

2. This Directive shall not apply to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air.

Article 4

General obligations

1. Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively.

2. Any person shall, before submitting a notification under part B or part C, carry out an environmental risk assessment. The information which may be necessary to carry out the environmental risk assessment is laid down in Annex III. Member States and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment. This phasing out shall take place by the 31 December 2004 in the case of GMOs placed on the market according to part C and by 31 December 2008 in the case of GMOs authorised under part B.

3. Member States and where appropriate the Commission shall ensure that potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms, are accurately assessed on a case-by-case basis. This assessment shall be conducted in accordance with Annex II taking into account the environmental impact according to the nature of the organism introduced and the receiving environment.

4. Member States shall designate the competent authority or authorities responsible for complying with the requirements of this Directive. The competent authority shall examine notifications under part B and part C for compliance with the requirements of this Directive and whether the assessment provided for in paragraph 2 is appropriate.

5. Member States shall ensure that the competent authority organises inspections and other control measures as appropriate, to ensure compliance with this Directive. In the event of a release of GMO(s) or placing on the market as or in products for which no authorisation was given, the Member

State concerned shall ensure that necessary measures are taken to terminate the release or placing on the market, to initiate remedial action if necessary, and to inform its public, the Commission and other Member States.

6. Member States shall take measures to ensure traceability, in line with the requirements laid down in Annex IV, at all stages of the placing on the market of GMOs authorised under part C.

PART B

DELIBERATE RELASE OF GMOs FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET

Article 5

1. Articles 6 to 11 shall not apply to medicinal substances and compunds for human use consisting of, or containing, a GMO or combination of GMOs provided that their deliberate release for any purpose other than that of being placed on the market is authorised by Community legislation which provides:

(a) for a specific environmental risk assessment in accordance with Annex II and on the basis of the type of information specified in Annex III without prejudice to additional requirements provided for by the said legislation;

(b) for explicit consent prior to release;

(c) for a monitoring plan in accordance with the relevant parts of Annex III, with a view to detecting the effects of the GMO or GMOs on human health or the environment;

(d) in an appropriate manner for requirements relating to treatment of new items of information, information to the public, information on the results of releases, and exchanges of information at least equivalent to those contained in this Directive and in the measures taken in accordance therewith.

2. Assessment of the risks to the environment presented by such substances and compounds shall be carried out in coordination with the national and Community authorities mentioned in this Directive.

3. Procedures ensuring conformity of the specific environmental risk assessment and equivalence with the provisions of this Directive must be provided for by the said legislation, which must refer to this Directive.

Article 6

Standard authorisation procedure

1. Without prejudice to Article 5, any person must, before undertaking a deliberate release of a GMO or of a combination of GMOs, submit a notification to the competent authority of the Member State within whose territory the release is to take place.

2. The notification referred to in paragraph 1 shall include:

(a) a technical dossier supplying the information specified in Annex III necessary for carrying out the environmental risk assessment of the deliberate release of a GMO or combination of GMOs, in particular:

(i) general information including information on personnel and training,

(ii) information relating to the GMO(s),

(iii) information relating to the conditions of release and the potential receiving environment,

(iv) information on the interactions between the GMO(s) and the environment,

(v) a plan for monitoring in accordance with the relevant parts of Annex III in order to identify effects of the GMO(s) on human health or the environment,

(vi) information on control, remediation methods, waste treatment and emergency response plans,

(vii) a summary of the dossier;

(b) the environmental risk assessment and the conclusions required in Annex II, section D, together with any bibliographic reference and indications of the methods used.

3. The notifier may refer to data or results from notifications previously submitted by other notifiers, provided that the information, data and results are non confidential or these notifiers have given their agreement in writing, or may submit additional information he considers relevant.

4. The competent authority may accept that releases of the same GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification.

5. The competent authority shall acknowledge the date of receipt of the notification and, having considered, where appropriate, any observations by other Member States made in accordance with Article 11, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with this Directive and that the release may proceed; or

(b) indicating that the release does not fulfil the conditions of this Directive and that notification is therefore rejected.

6. For the purpose of calculating the 90 day period referred to in paragraph 5, no account shall be taken of any periods of time during which the competent authority:

(a) is awaiting further information which it may have requested from the notifier, or

(b) is carrying out a public inquiry or consultation in accordance with Article 9; this public inquiry or consultation shall not prolong the 90 day period referred to in paragraph 5 by more than 30 days.

7. If the competent authority requests new information it must simultaneously give its reasons for so doing.

8. The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.

9. Member States shall ensure that no material derived from GMOs which are deliberately released in accordance with part B is placed on the market, unless in accordance with part C.

Article 7

Differentiated procedures

1. If sufficient experience has been obtained of releases of certain GMOs in certain ecosystems and the GMOs concerned meet the criteria set out in Annex V, a competent authority may submit to the Commission a reasoned proposal for the application of differentiated procedures to such types of GMOs.

2. Following its own initiative or at the latest 30 days following the receipt of a competent authority's proposal, the Commission shall,

(a) forward the proposal to the competent authorities, which may, within 60 days, present observations and at the same time;

(b) make available the proposal to the public which may, within 60 days, make comments; and

(c) consult the relevant Scientific Committee(s) which may, within 60 days give an opinion.

3. A decision shall be taken on each proposal in accordance with the procedure laid down in Article 30(2). This decision shall establish the minimum amount of technical information from Annex III necessary for evaluating any foreseeable risks from the release, in particular:

(a) information relating to the GMO(s);

(b) information relating to the conditions of release and the potential receiving environment;

(c) information on the interactions between the GMO(s) and the environment;

(d) the environmental risk assessment.

4. This decision shall be taken within 90 days of the date of the Commission's proposal or of receipt of the competent authority's proposal. This 90 day period shall not take into account the period of time during which the Commission is awaiting the observations of competent authorities, the comments of the public or the opinion of Scientific Committees, as provided for in paragraph 2.

5. The decision taken under paragraphs 3 and 4 shall provide that the notifier may proceed with the release only when he has received the written consent of the competent authority. The notifier shall proceed with the release in conformity with any conditions required in this consent.

The decision taken under paragraphs 3 and 4 may provide that releases of a GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification.

6. Without prejudice to paragraphs 1 to 5, Commission Decision 94/730/EC of 4 November 1994 establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC [1] shall continue to apply.

7. Where a Member State decides to make use or not of a procedure established in a decision taken in accordance with paragraphs 3 and 4 for releases of GMOs within its territory, it shall inform the Commission thereof.

Article 8

Handling of modifications and new information

1. In the event of any modification of, or unintended change to, the deliberate release of a GMO or of a combination of GMOs which could have consequences with regard to risks for human health and the environment after the competent authority has given its written consent, or if new information has become available on such risks, either while the notification is being examined by the competent authority of a Member State or after that authority has given its written consent, the notifier shall immediately:

[1] OJ L 292, 12.11.1994, p. 31.

(a) take the measures necessary to protect human health and the environment;

(b) inform the competent authority in advance of any modification or as soon as the unintended change is known or the new information is available;

(c) revise the measures specified in the notification.

2. If information becomes available to the competent authority referred to in paragraph 1 which could have significant consequences with regard to risks for human health and the environment or under the circumstances described in paragraph 1, the competent authority shall evaluate such information and make it available to the public. It may require the notifier to modify the conditions of, suspend or terminate the deliberate release and shall inform the public thereof.

Article 9

Consultation of and information to the public

1. Member States shall, without prejudice to the provisions of Articles 7 and 25, consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, Member States shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion.

2. Without prejudice to the provisions of Article 25:

— Member States shall make available to the public information on all part B releases of GMOs in their territory;

— the Commission shall make available to the public the information contained in the system of exchange of information pursuant to Article 11.

Article 10

Reporting by notifiers on releases

After completion of a release, and thereafter, at any intervals laid down in the consent on the basis of the results of the environmental risk assessment, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with, where appropriate, particular reference to any kind of product that the notifier intends to notify at a later stage. The format for the presentation of this result shall be established in accordance with the procedure laid down in Article 30(2).

Article 11

Exchange of information between competent authorities and the Commission

1. The Commission shall set up a system of exchange of the information contained in the notifications. The competent authorities shall send to the Commission, within 30 days of its receipt, a summary of each notification received under Article 6. The format of this summary shall be established and modified if appropriate in accordance with the procedure laid down in Article 30(2).

2. The Commission shall, at the latest 30 days following their receipt, forward these summaries to the other Member States, which may, within 30 days, present observations through the Commission or directly. At its request, a Member State shall be permitted to receive a copy of the full notification from the competent authority of the relevant Member State.

3. The competent authorities shall inform the Commission of the final decisions taken in compliance with Article 6(5), including where relevant the reasons for rejecting a notification, and of the results of the releases received in accordance with Article 10.

4. For the releases of GMOs referred to in Article 7, once a year Member States shall send a list of GMOs which have been released on their territory and a list of notifications that were rejected to the Commission, which shall forward them to the competent authorities of the other Member States.

PART C

PLACING ON THE MARKET OF GMOs AS OR IN PRODUCTS

Article 12

Sectoral legislation

1. Articles 13 to 24 shall not apply to any GMO as or in products as far as they are authorised by Community legislation which provides for a specific environmental risk assessment carried out in accordance with the principles set out in Annex II and on the basis of information specified in Annex III without prejudice to additional requirements provided for by the Community legislation mentioned above, and for requirements as regards risk management, labelling, monitoring as appropriate, information to the public and safeguard clause at least equivalent to that laid down in this Directive.

2. As far as Council Regulation (EEC) No 2309/93 is concerned, Articles 13 to 24 of this Directive shall not apply to any GMO as or in products as far as they are authorised by that Regulation provided that a specific environmental risk assessment is carried out in accordance with the principles set out in Annex II to this Directive and on the basis of the type of information specified in Annex III to this Directive without prejudice to other relevant requirements as regards risk assessment, risk management, labelling, monitoring as appropriate, information to the public and safeguard clause provided by Community legislation concerning medicinal products for human and veterinary use.

3. Procedures ensuring that the risk assessment, requirements regarding risk management, labelling, monitoring as appropriate, information to the public and safeguard clause are equivalent to those laid down in this Directive shall be

introduced, in a Regulation of the European Parliament and of the Council. Future sectoral legislation based on the provisions of that Regulation shall make a reference to this Directive. Until the Regulation enters into force, any GMO as or in products as far as they are authorised by other Community legislation shall only be placed on the market after having been accepted for placing on the market in accordance with this Directive.

4. During evaluation of the requests for the placing on the market of the GMOs referred to in paragraph 1, the bodies established by the Community under this Directive and by Member States for the purpose of implementing this Directive shall be consulted.

Article 13

Notification procedure

1. Before a GMO or a combination of GMOs as or in products is placed on the market, a notification shall be submitted to the competent authority of the Member State where such a GMO is to be placed on the market for the first time. The competent authority shall acknowledge the date of receipt of the notification and immediately forward the summary of the dossier referred to in paragraph 2(h) to the competent authorities of the other Member States and the Commission.

The competent authority shall without delay examine whether the notification is in accordance with paragraph 2 and shall, if necessary, ask the notifier for additional information.

When the notification is in accordance with paragraph 2, and at the latest when it sends its assessment report in accordance with Article 14(2), the competent authority shall forward a copy of the notification to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

2. The notification shall contain:

(a) the information required in Annexes III and IV. This information shall take into account the diversity of sites of use of the GMO as or in a product and shall include information on data and results obtained from research and developmental releases concerning the impact of the release on human health and the environment;

(b) the environmental risk assessment and the conclusions required in Annex II, section D;

(c) the conditions for the placing on the market of the product, including specific conditions of use and handling;

(d) with reference to Article 15(4), a proposed period for the consent which should not exceed ten years;

(e) a plan for monitoring in accordance with Annex VII, including a proposal for the time-period of the monitoring plan; this time-period may be different from the proposed period for the consent;

(f) a proposal for labelling which shall comply with the requirements laid down in Annex IV. The labelling shall clearly state that a GMO is present. The words 'this product contains genetically modified organisms' shall appear either on a label or in an accompanying document;

(g) a proposal for packaging which shall comprise the requirements laid down in Annex IV;

(h) a summary of the dossier. The format of the summary shall be established in accordance with the procedure laid down in Article 30(2).

If on the basis of the results of any release notified under part B, or on other substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a GMO as or in a product do not pose a risk to human health and the environment, he may propose to the competent authority not to provide part or all of the information required in Annex IV, section B.

3. The notifier shall include in this notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by the notifier either inside or outside the Community.

4. The notifier may also refer to data or results from notifications previously submitted by other notifiers or submit additional information he considers relevant, provided that the information, data and results are non-confidential or these notifiers have given their agreement in writing.

5. In order for a GMO or combination of GMOs to be used for a purpose different from that already specified in a notification, a separate notification shall be submitted.

6. If new information has become available with regard to the risks of the GMO to human health or the environment, before the written consent is granted, the notifier shall immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof. In addition, the notifier shall revise the information and conditions specified in the notification.

Article 14

Assessment report

1. On receipt and after acknowledgement of the notification in accordance with Article 13(2), the competent authority shall examine it for compliance with this Directive.

2. Within 90 days after receipt of the notification the competent authority shall:

— prepare an assessment report and send it to the notifier. A subsequent withdrawal by the notifier shall be without prejudice to any further submission of the notification to another competent authority;

— in the case referred to in paragraph 3(a), send its report, together with the information referred to in paragraph 4 and any other information on which it has based its report, to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

In the case referred to paragraph 3(b), the competent authority shall send its report, together with the information referred to in paragraph 4 and any other information on which it has based its report, to the Commission no earlier than 15 days after sending the assessment report to the notifier and no later than 105 days after receipt of the notification. The Commission shall, within 30 days of its receipt, forward the report to the competent authorities of the other Member States.

3. The assessment report shall indicate whether:

(a) the GMO(s) in question should be placed on the market and under which conditions; or

(b) the GMO(s) in question should not be placed on the market.

The assessment reports shall be established in accordance with the guidelines laid down in Annex VI.

4. For the purpose of calculating the 90 day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account. The competent authority shall state the reasons in any request for further information.

Article 15

Standard procedure

1. In the cases referred to in Article 14(3), a competent authority or the Commission may ask for further information, make comments or present reasoned objections to the placing on the market of the GMO(s) in question within a period of 60 days from the date of circulation of the assessment report.

Comments or reasoned objections and replies shall be forwarded to the Commission which shall immediately circulate them to all competent authorities.

The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 105 days from the date of circulation of the assessment report.

Any periods of time during which further information from the notifier is awaited shall not be taken into account for the purpose of calculating the final 45 day period for arriving at an agreement. Reasons shall be stated in any request for further information.

2. In the case referred to in Article 14(3)(b), if the competent authority which prepared the report decides that the GMO(s) should not be placed on the market, the notification shall be rejected. This decision shall state the reasons.

3. If the competent authority which prepared the report decides that the product may be placed on the market, in the absence of any reasoned objection from a Member State or the Commission within 60 days following the date of circulation of the assessment report referred to in Article 14(3)(a) or if outstanding issues are resolved within the 105 day period referred to in paragraph 1, the competent authority which prepared the report shall give consent in writing for placing on the market, shall transmit it to the notifier and shall inform the other Member States and the Commission thereof within 30 days.

4. The consent shall be given for a maximum period of ten years starting from the date on which the consent is issued.

For the purpose of approval of a GMO or a progeny of that GMO intended only for the marketing of their seeds under the relevant Community provisions, the period of the first consent shall end at the latest ten years after the date of the first inclusion of the first plant variety containing the GMO on an official national catalogue of plant varieties in accordance with Council Directives 70/457/EEC ([1]) and 70/458/EEC ([2]).

In the case of forest reproductive material, the period of the first consent shall end at the latest ten years after the date of the first inclusion of basic material containing the GMO on an official national register of basic material in accordance with Council Directive 1999/105/EC ([3]).

Article 16

Criteria and information for specified GMOs

1. A competent authority, or the Commission on its own initiative, may make a proposal on criteria and information requirements to be met for the notification, by way of derogation from Article 13, for the placing on the market of certain types of GMOs as or in products.

([1]) Council Directive 70/457/EEC of 29 September 1970 on the common catalogue of varieties of agricultural plant species (OJ L 225, 12.10.1970, p. 1). Directive as last amended by Directive 98/96/EC (OJ L 25, 1.2.1999, p. 27).

([2]) Council Directive 70/458/EEC of 29 September 1970 on the marketing of vegetable seed (OJ L 225, 12.10.1970, p. 7). Directive as last amended by Directive 98/96/EC.

([3]) Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material (OJ L 11, 15.1.2000, p. 17).

2. These criteria and information requirements as well as any appropriate requirements for a summary shall be adopted, after consultation of the relevant Scientific Committee(s), in accordance with the procedure laid down in Article 30(2). The criteria and the information requirements shall be such as to ensure a high level of safety to human health and the environment and be based on the scientific evidence available on such safety and on the experience gained from the release of comparable GMOs.

The requirements set out in Article 13(2) shall be replaced by those adopted above, and the procedure set out in Article 13(3), (4), (5) and (6) and Articles 14 and 15 shall apply.

3. Before the procedure laid down in Article 30(2) for a decision on criteria and information requirements referred to in paragraph 1 is initiated, the Commission shall make the proposal available to the public. The public may make comments to the Commission within 60 days. The Commission shall forward any such comments, together with an analysis, to the Committee set up pursuant to Article 30.

Article 17

Renewal of consent

1. By way of derogation from Articles 13, 14 and 15, the procedure set out in paragraphs 2 to 9 shall be applied to the renewal of:

(a) consents granted under part C; and

(b) before 17 October 2006 of consents granted under Directive 90/220/EEC for placing on the market of GMOs as or in products before 17 October 2002,

2. At the latest nine months before the expiry of the consent, for the consents referred to in paragraph 1(a), and before 17 October 2006, for the consents referred to in paragraph 1(b), the notifier under this Article shall submit a notification to the competent authority which received the original notification, which shall contain:

(a) a copy of the consent to the placing on the market of the GMOs;

(b) a report on the results of the monitoring which was carried out according to Article 20. In the case of consents referred to in paragraph 1(b), this report shall be submitted when the monitoring was carried out;

(c) any other new information which has become available with regard to the risks of the product to human health and/or the environment; and

(d) as appropriate, a proposal for amending or complementing the conditions of the original consent, *inter alia* the conditions concerning future monitoring and the time limitation of the consent.

The competent authority shall acknowledge the date of receipt of the notification and when the notification is in accordance with this paragraph it shall without delay forward a copy of the notification and its assessment report to the Commission, which shall, within 30 days of their receipt, forward them to the competent authorities of the other Member States. It shall also send its assessment report to the notifier.

3. The assessment report shall indicate whether:

(a) the GMO(s) should remain on the market and under which conditions; or

(b) the GMO(s) should not remain on the market.

4. The other competent authorities or the Commission may ask for further information, make comments, or present reasoned objections within a period of 60 days from the date of circulation of the assessment report.

5. All comments, reasoned objections and replies shall be forwarded to the Commission which shall immediately circulate them to all competent authorities.

6. In the case of paragraph 3(a) and in the absence of any reasoned objection from a Member State or the Commission within 60 days from the date of circulation of the assessment report, the competent authority which prepared the report shall transmit to the notifier the final decision in writing and shall inform the other Member States and the Commission thereof within 30 days. The validity of the consent should not, as a general rule, exceed ten years and may be limited or extended as appropriate for specific reasons.

7. The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 75 days from the date of circulation of the assessment report.

8. If outstanding issues are resolved within the 75 day period referred to in paragraph 7, the competent authority which prepared the report shall transmit to the notifier its final decision in writing and shall inform the other Member States and the Commission thereof within 30 days. The validity of the consent may be limited as appropriate.

9. Following a notification for the renewal of a consent in accordance with paragraph 2, the notifier may continue to place the GMOs on the market under the conditions specified in that consent until a final decision has been taken on the notification.

Article 18

Community procedure in case of objections

1. In cases where an objection is raised and maintained by a competent authority or the Commission in accordance with Articles 15, 17 and 20, a decision shall be adopted and published within 120 days in accordance with the procedure laid down in Article 30(2). This decision shall contain the same information as in Article 19(3).

For the purpose of calculating the 120 day period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the Scientific Committee which has been consulted in accordance with Article 28 shall not be taken into account. The Commission shall state reasons in any request for further information and inform the competent authorities of its requests to the notifier. The period of time during which the Commission is awaiting the opinion of the Scientific Committee shall not exceed 90 days.

The period of time that the Council takes to act in accordance with the procedure laid down in Article 30(2) shall not be taken into account.

2. Where a favourable decision has been taken, the competent authority which prepared the report shall give consent in writing to the placing on the market or to the renewal of the consent, shall transmit it to the notifier and shall inform the other Member States and the Commission thereof within 30 days following the publication or notification of the decision.

Article 19

Consent

1. Without prejudice to requirements under other Community legislation, only if a written consent has been given for the placing on the market of a GMO as or in a product may that product be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.

2. The notifier may proceed with the placing on the market only when he has received the written consent of the competent authority in accordance with Articles 15, 17 and 18, and in conformity with any conditions required in that consent.

3. The written consent referred to in Articles 15, 17 and 18 shall, in all cases, explicitly specify:

(a) the scope of the consent, including the identity of the GMO(s) to be placed on the market as or in products, and their unique identifier;

(b) the period of validity of the consent;

(c) the conditions for the placing on the market of the product, including any specific condition of use, handling and packaging of the GMO(s) as or in products, and conditions for the protection of particular ecosystems/environments and/or geographical areas;

(d) that, without prejudice to Article 25, the notifier shall make control samples available to the competent authority on request;

(e) the labelling requirements, in compliance with the requirements laid down in Annex IV. The labelling shall clearly state that a GMO is present. The words 'This product contains genetically modified organisms' shall appear either on a label or in a document accompanying the product or other products containing the GMO(s);

(f) monitoring requirements in accordance with Annex VII, including obligations to report to the Commission and competent authorities, the time period of the monitoring plan and, where appropriate, any obligations on any person selling the product or any user of it, *inter alia*, in the case of GMOs grown, concerning a level of information deemed appropriate on their location.

4. Member States shall take all necessary measures to ensure that the written consent and the decision referred to in Article 18, where applicable, are made accessible to the public and that the conditions specified in the written consent and the decision, where applicable, are complied with.

Article 20

Monitoring and handling of new information

1. Following the placing on the market of a GMO as or in a product, the notifier shall ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent. The reports of this monitoring shall be submitted to the Commission and the competent authorities of the Member States. On the basis of these reports, in accordance with the consent and within the framework for the monitoring plan specified in the consent, the competent authority which received the original notification may adapt the monitoring plan after the first monitoring period.

2. If new information has become available, from the users or other sources, with regard to the risks of the GMO(s) to human health or the environment after the written consent has been given, the notifier shall immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof.

In addition, the notifier shall revise the information and conditions specified in the notification.

3. If information becomes available to the competent authority which could have consequences for the risks of the GMO(s) to human health or the environment, or under the circumstances described in paragraph 2, it shall immediately forward the information to the Commission and the competent authorities of the other Member States and may avail itself of the provisions in Articles 15(1) and 17(7) where appropriate, when the information has become available before the written consent.

When the information has become available after the consent has been given, the competent authority shall within 60 days after receipt of the new information, forward its assessment report indicating whether and how the conditions of the consent should be amended or the consent should be terminated to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

Comments or reasoned objections to further placing on the market of the GMO or on the proposal for amending the conditions of the consent shall, within 60 days following the circulation of the assessment report, be forwarded to the Commission which shall immediately forward them to all competent authorities.

The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 75 days from the date of circulation of the assessment report.

In the absence of any reasoned objection from a Member State or the Commission within 60 days following the date of circulation of the new information or if outstanding issues are resolved within 75 days, the competent authority which prepared the report shall amend the consent as proposed, shall transmit the amended consent to the notifier and shall inform the other Member States and the Commission thereof within 30 days.

4. So as to ensure its transparency, the results of the monitoring carried out under part C of the Directive shall be made publicly available.

Article 21

Labelling

1. Member States shall take all necessary measures to ensure that at all stages of the placing on the market, the labelling and packaging of GMOs placed on the market as or in products comply with the relevant requirements specified in the written consent referred to in Articles 15(3), 17(5) and (8), 18(2) and 19(3).

2. For products where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded, a minimum threshold may be established below which these products shall not have to be labelled according to the provision in paragraph 1. The threshold levels shall be established according to the product concerned, under the procedure laid down in Article 30(2).

Article 22

Free circulation

Without prejudice to Article 23, Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive.

Article 23

Safeguard clause

1. Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory.

The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.

The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.

2. A decision shall be taken on the matter within 60 days in accordance with the procedure laid down in Article 30(2). For the purpose of calculating the 60 day period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the Scientific Committee(s) which has/have been consulted shall not be taken into account. The period of time during which the Commission is awaiting the opinion of the Scientific Committee(s) consulted shall not exceed 60 days.

Likewise, the period of time the Council takes to act in accordance with the procedure laid down in Article 30(2) shall not be taken into account.

Article 24

Information to the public

1. Without prejudice to Article 25, upon receipt of a notification in accordance with Article 13(1), the Commission shall immediately make available to the public the summary referred to in Article 13(2)(h). The Commission shall also make available to the public assessment reports in the case referred to in Article 14(3)(a). The public may make comments to the Commission within 30 days. The Commission shall immediately forward the comments to the competent authorities.

2. Without prejudice to Article 25, for all GMOs which have received written consent for placing on the market or whose placing on the market was rejected as or in products under this Directive, the assessment reports carried out for these GMOs and the opinion(s) of the Scientific Committees consulted shall be made available to the public. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

PART D

FINAL PROVISIONS

Article 25

Confidentiality

1. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the data received.

2. The notifier may indicate the information in the notification submitted under this Directive, the disclosure of which might harm his competitive positionand which should therefore be treated as confidential. Verifiable justification must be given in such cases.

3. The competent authority shall, after consultation with the notifier, decide which information will be kept confidential and shall inform the notifier of its decisions.

4. In no case may the following information when submitted according to Articles 6, 7, 8, 13, 17, 20 or 23 be kept confidential:

— general description of the GMO or GMOs, name and address of the notifier, purpose of the release, location of release and intended uses;

— methods and plans for monitoring of the GMO or GMOs and for emergency response;

— environmental risk assessment.

5. If, for whatever reasons, the notifier withdraws the notification, the competent authorities and the Commission must respect the confidentiality of the information supplied.

Article 26

Labelling of GMOs referred to in Article 2(4), second subparagraph

1. The GMOs to be made available for operations referred to under Article 2(4), second subparagraph, shall be subject to adequate labelling requirements in accordance with the relevant sections of Annex IV in order to provide for clear information, on a label or in an accompanying document, on the presence of GMOs. To that effect the words 'This product contains genetically modified organisms' shall appear either on a label or in an accompanying document.

2. The conditions for the implementation of paragraph 1 shall, without duplicating or creating inconsistencies with existing labelling provisions laid down in existing Community legislation, be determined in accordance with the procedure laid down in Article 30(2). In doing so, account should be taken, as appropriate, of labelling provisions established by Member States in accordance with Community legislation.

Article 27

Adaptation of Annexes to technical progress

Sections C and D of Annex II, Annexes III to VI, and section C of Annex VII shall be adapted to technical progress in accordance with the procedure laid down in Article 30(2).

Article 28

Consultation of Scientific Committee(s)

1. In cases where an objection as regards the risks of GMOs to human health or to the environment is raised by a competent authority or the Commission and maintained in accordance with Article 15(1), 17(4), 20(3) or 23, or where the assessment report referred to in Article 14 indicates that the GMO should not be placed on the market, the relevant Scientific Committee(s) shall be consulted by the Commission, on its own initiative or at the request of a Member State, on the objection.

2. The relevant Scientific Committee(s) may also be consulted by the Commission, on its own initiative or at the request of a Member State, on any matter under this Directive that may have an adverse effect on human health and the environment.

3. The administrative procedures laid down in this Directive shall not be affected by paragraph 2.

Article 29

Consultation of Committee(s) on Ethics

1. Without prejudice to the competence of Member States as regards ethical issues, the Commission shall, on its own initiative or at the request of the European Parliament or the Council, consult any committee it has created with a view to obtaining its advice on the ethical implications of biotechnology, such as the European Group on Ethics in Science and New Technologies, on ethical issues of a general nature.

This consultation may also take place at the request of a Member State.

2. This consultation is conducted under clear rules of openness, transparency and public accessibility. Its outcome shall be accessible to the public.

3. The administrative procedures provided for in this Directive shall not be affected by paragraph 1.

Article 30

Committee procedure

1. The Commission shall be assisted by a committee.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The committee shall adopt its own rules of procedure.

Article 31

Exchange of information and reporting

1. Member States and the Commission shall meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release and the placing on the market of GMOs. This information exchange shall also cover experience gained from the implementation of Article 2(4), second subparagraph, environmental risk assessment, monitoring and the issue of consultation and information of the public.

Where necessary, guidance on the implementation of Article 2(4), second subparagraph, may be provided by the committee established under Article 30(1).

2. The Commission shall establish one or several register(s) for the purpose of recording the information on genetic modifications in GMOs mentioned in point A No 7 of Annex IV. Without prejudice to Article 25, the register(s) shall include a part which is accessible to the public. The detailed arrangements for the operation of the register(s) shall be decided in accordance with the procedure laid down in Article 30(2).

3. Without prejudice to paragraph 2 and point A No 7 of Annex IV,

(a) Member States shall establish public registers in which the location of the release of the GMOs under part B is recorded.

(b) Member States shall also establish registers for recording the location of GMOs grown under part C, *inter alia* so that the possible effects of such GMOs on the environment may be monitored in accordance with the provisions of Articles 19(3)(f) and 20(1). Without prejudice to such provisions in Articles 19 and 20, the said locations shall:

— be notified to the competent authorities, and

— be made known to the public

in the manner deemed appropriate by the competent authorities and in accordance with national provisions.

4. Every three years, Member States shall send the Commission a report on the measures taken to implement the provisions of this Directive. This report shall include a brief factual report on their experience with GMOs placed on the market in or as products under this Directive.

5. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 4.

6. The Commission shall send to the European Parliament and the Council, in 2003 and thereafter every three years, a report on the experience of Member States with GMOs placed on the market under this Directive.

7. When submitting this report in 2003, the Commission shall at the same time submit a specific report on the operation of part B and part C including an assessment of:

(a) all its implications, particularly to take account of the diversity of European ecosystems and the need to complement the regulatory framework in this field;

(b) the feasibility of various options to improve further the consistency and efficiency of this framework, including a centralised Community authorisation procedure and the arrangements for the final decision making by the Commission;

(c) whether sufficient experience has accumulated on the implementation of part B differentiated procedures to justify a provision on implicit consent in these procedures

and on part C to justify the application of differentiated procedures; and

(d) the socioeconomic implications of deliberate releases and placing on the market of GMOs.

8. The Commission shall send to the European Parliament and the Council every year, a report on the ethical issues referred to in Article 29(1); this report may be accompanied, if appropriate, by a proposal with a view to amending this Directive.

Article 32

Implementation of the Cartagena Protocol on biosafety

1. The Commission is invited to bring forward as soon as possible and in any case before July 2001 a legislative proposal for implementing in detail the Cartagena Protocol on biosafety. The proposal shall complement and, if necessary, amend the provisions of this Directive.

2. This proposal shall, in particular, include appropriate measures to implement the procedures laid down in the Cartagena Protocol and, in accordance with the Protocol, require Community exporters to ensure that all requirements of the Advance Informed Agreement Procedure, as set out in Articles 7 to 10, 12 and 14 of the Cartagena Protocol, are fulfilled.

Article 33

Penalties

Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive. Those penalties shall be effective, proportionate and dissuasive.

Article 34

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 17 October 2002. They shall forthwith inform the Commission thereof.

When Member States adopt these measures they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the texts of the main provisions of domestic law which they adopt in the field covered by this Directive.

Article 35

Pending notifications

1. Notifications concerning placing on the market of GMOs as or in products received pursuant to Directive 90/220/EEC, and in respect of which the procedures of that Directive have not been completed by 17 October 2002 shall be subject to the provisions of this Directive.

2. By 17 January 2003 notifiers shall have complemented their notification in accordance with this Directive.

Article 36

Repeal

1. Directive 90/220/EEC shall be repealed on 17 October 2002.

2. References made to the repealed Directive shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex VIII.

Article 37

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 38

This Directive is addressed to the Member States.

Done at Brussels, 12 March 2001.

For the European Parliament	*For the Council*
N. FONTAINE	L. PAGROTSKY
The President	*The President*

ANNEX I A

TECHNIQUES REFERRED TO IN ARTICLE 2(2)

PART 1

Techniques of genetic modification referred to in Article 2(2)(a) are *inter alia:*

(1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2

Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:

(1) in vitro fertilisation,

(2) natural processes such as: conjugation, transduction, transformation,

(3) polyploidy induction.

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

ANNEX II

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

This Annex describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the environmental risk assessment (e.r.a.) referred to in Articles 4 and 13. It will be supplemented by guidance notes to be developed in accordance with the procedure laid down in Article 30(2). These guidance notes shall be completed by 17 October 2002.

With a view to contributing to a common understanding of the terms 'direct, indirect, immediate and delayed' when implementing this Annex, without prejudice to further guidance in this respect and in particular as regards the extent to which indirect effects can and should be taken into account, these terms are described as follows:

— 'direct effects' refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events;

— 'indirect effects' refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management.

Observations of indirect effects are likely to be delayed;

— 'immediate effects' refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;

— 'delayed effects' refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

A general principle for environmental risk assessment is also that an analysis of the 'cumulative long-term effects' relevant to the release and the placing on the market is to be carried out. 'Cumulative long-term effects' refers to the accumulated effects of consents on human health and the environment, including *inter alia* flora and fauna, soil fertility, soil degradation of organic material, the feed/ food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

A. **Objective**

The objective of an e.r.a. is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have. The e.r.a. should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.

B. **General Principles**

In accordance with the precautionary principle, the following general principles should be followed when performing the e.r.a.:

— identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;

— the e.r.a. should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;

— the e.r.a. should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the GMOs concerned, their intended use and the potential receiving environment, taking into account, i.a., GMOs already in the environment;

— if new information on the GMO and its effects on human health or the environment becomes available, the e.r.a. may need to be readdressed in order to:

— determine whether the risk has changed;

— determine whether there is a need for amending the risk management accordingly.

C. **Methodology**

C.1. Characteristics of GMOs and releases

Depending on the case the e.r.a. has to take into account the relevant technical and scientific details regarding characteristics of:

— the recipient or parental organism(s);

— the genetic modification(s), be it inclusion or deletion of genetic material, and relevant information on the vector and the donor;

— the GMO;

— the intended release or use including its scale;

— the potential receiving environment; and

— the interaction between these.

Information from releases of similar organisms and organisms with similar traits and their interaction with similar environments can assist the e.r.a.

C.2. Steps in the e.r.a.

In drawing conclusions for the e.r.a. referred to in Articles 4, 6, 7 and 13 the following points should be addressed:

1. *Identification of characteristics which may cause adverse effects:*

Any characteristics of the GMOs linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified. A comparison of the characteristics of the GMO(s) with those of the non-modified organism under corresponding conditions of the release or use, will assist in identifying the particular potential adverse effects arising from the genetic modification. It is important not to discount any potential adverse effect on the basis that it is unlikely to occur.

Potential adverse effects of GMOs will vary from case to case, and may include:

— disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C.2(i) in Annex III A, and B 7 in Annex III B);

— disease to animals and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11. and II.C.2(i) in Annex III A, and B 7 and D 8 in Annex III B);

— effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see for example items IV B 8, 9 and 12 in Annex III A);

— altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;

— compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A.11(e) and II.C.2(i)(iv) in Annex III A);

— effects on biogeochemistry(biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11(f) and IV.B.15 in Annex III A, and D 11 in Annex III B).

Adverse effects may occur directly or indirectly through mechanisms which may include:

— the spread of the GMO(s) in the environment,

— the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not,

— phenotypic and genetic instability,

— interactions with other organisms,

— changes in management, including, where applicable, in agricultural practices.

2. *Evaluation of the potential consequences of each adverse effect, if it occurs*

The magnitude of the consequences of each potential adverse effect should be evaluated.

This evaluation should assume that such an adverse effect will occur. The magnitude of the consequences is likely to be influenced by the environment into which the GMO(s) is (are) intended to be released and the manner of the release.

3. *Evaluation of the likelihood of the occurrence of each identified potential adverse effect*

A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which the GMO(s) is intended to be released, and the manner of the release.

4. *Estimation of the risk posed by each identified characteristic of the GMO(s)*

An estimation of the risk to human health or the environment posed by each identified characteristic of the GMO which has the potential to cause adverse effects should be made as far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

5. *Application of management strategies for risks from the deliberate release or marketing of GMO(s)*

The risk assessment may identify risks that require management and how best to manage them, and a risk management strategy should be defined.

6. *Determination of the overall risk of the GMO(s)*

An evaluation of the overall risk of the GMO(s) should be made taking into account any risk management strategies which are proposed.

D. **Conclusions on the potential environmental impact from the release or the placing on the market of GMOs**

On the basis of an e.r.a. carried out in accordance with the principles and methodology outlined in sections B and C, information on the points listed in sections D1 or D2 should be included, as appropriate, in notifications with a view to assisting in drawing conclusions on the potential environmental impact from the release or the placing on the market of GMOs:

D.1. In the case of GMOs other than higher plants

1. Likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of the proposed release(s).

2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of the proposed release(s).

3. Potential for gene transfer to other species under conditions of the proposed release of the GMO and any selective advantage or disadvantage conferred to those species.

4. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO and target organisms (if applicable).

5. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.

D.2. In the case of genetically modified higher plants (GMHP)

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

2. Any selective advantage or disadvantage conferred to the GMHP.

3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.

4. Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable).

5. Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

ANNEX III

INFORMATION REQUIRED IN THE NOTIFICATION

A notification referred to in part B or part C of the Directive is to include, as appropriate, the information set out below in the sub-Annexes.

Not all the points included will apply to every case. It is to be expected that individual notifications will address only the particular subset of considerations which is appropriate to individual situations.

The level of detail required in response to each subset of considerations is also likely to vary according to the nature and the scale of the proposed release.

Future developments in genetic modification may necessitate adapting this Annex to technical progress or developing guidance notes on this Annex. Further differentiation of information requirements for different types of GMOs, for example single celled organisms, fish or insects, or for particular use of GMOs like the development of vaccines, may be possible once sufficient experience with notifications for the release of particular GMOs has been gained in the Community.

The description of the methods used or the reference to standardised or internationally recognised methods shall also be mentioned in the dossier, together with the name of the body or bodies responsible for carrying out the studies.

Annex III A applies to releases of all types of genetically modified organisms other than higher plants. Annex III B applies to release of genetically modified higher plants.

The term 'higher plants' means plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

ANNEX III A

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

I. GENERAL INFORMATION

A. Name and address of the notifier (company or institute)

B. Name, qualifications and experience of the responsible scientist(s)

C. Title of the project

II. INFORMATION RELATING TO THE GMO

A. **Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):**

1. scientific name,
2. taxonomy,
3. other names (usual name, strain name, etc.),
4. phenotypic and genetic markers,
5. degree of relatedness between donor and recipient or between parental organisms,
6. description of identification and detection techniques,
7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,
8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts,
9. organisms with which transfer of genetic material is known to occur under natural conditions,
10. verification of the genetic stability of the organisms and factors affecting it,
11. pathological, ecological and physiological traits:
    (a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;
    (b) generation time in natural ecosystems, sexual and asexual reproductive cycle;
    (c) information on survival, including seasonability and the ability to form survival structures;
    (d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonise other organisms;
    (e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;
    (f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.
12. Nature of indigenous vectors:
    (a) sequence;
    (b) frequency of mobilisation;
    (c) specificity;
    (d) presence of genes which confer resistance.
13. History of previous genetic modifications.

B. **Characteristics of the vector**

1. nature and source of the vector,

2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO,

3. frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination,

4. information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. **Characteristics of the modified organism**

1. Information relating to the genetic modification:

   (a) methods used for the modification;

   (b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;

   (c) description of the insert and/or vector construction;

   (d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;

   (e) methods and criteria used for selection;

   (f) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

   (a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

   (b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;

   (c) stability of the organism in terms of genetic traits;

   (d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;

   (e) activity of the expressed protein(s);

   (f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;

   (g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

   (h) history of previous releases or uses of the GMO;

   (i) considerations for human health and animal health, as well as plant health:

      (i) toxic or allergenic effects of the GMOs and/or their metabolic products;

      (ii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

      (iii) capacity for colonisation;

(iv) if the organism is pathogenic to humans who are immunocompetent:

— diseases caused and mechanism of pathogenicity including invasiveness and virulence,

— communicability,

— infective dose,

— host range, possibility of alteration,

— possibility of survival outside of human host,

— presence of vectors or means of dissemination,

— biological stability,

— antibiotic resistance patterns,

— allergenicity,

— availability of appropriate therapies.

(v) other product hazards.

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. **Information on the release**

1. description of the proposed deliberate release, including the purpose(s) and foreseen products,
2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases,
3. preparation of the site previous to the release,
4. size of the site,
5. method(s) to be used for the release,
6. quantities of GMOs to be released,
7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities),
8. worker protection measures taken during the release,
9. post-release treatment of the site,
10. techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment,
11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B. **Information on the environment (both on the site and in the wider environment):**

1. geographical location and grid reference of the site(s) (in case of notifications under part C the site(s) of release will be the foreseen areas of use of the product),
2. physical or biological proximity to humans and other significant biota,
3. proximity to significant biotopes, protected areas, or drinking water supplies,
4. climatic characteristics of the region(s) likely to be affected,
5. geographical, geological and pedological characteristics,
6. flora and fauna, including crops, livestock and migratory species,
7. description of target and non-target ecosystems likely to be affected,

8. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release,

9. any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT

A. **Characteristics affecting survival, multiplication and dissemination**

1. biological features which affect survival, multiplication and dispersal,

2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.),

3. sensitivity to specific agents.

B. **Interactions with the environment**

1. predicted habitat of the GMOs,

2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses,

3. genetic transfer capability

   (a) postrelease transfer of genetic material from GMOs into organisms in affected ecosystems;

   (b) postrelease transfer of genetic material from indigenous organisms to the GMOs;

4. likelihood of postrelease selection leading to the expression of unexpected and/or undesirable traits in the modified organism,

5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify genetic stability,

6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.,

7. description of ecosystems to which the GMOs could be disseminated,

8. potential for excessive population increase in the environment,

9. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s),

10. identification and description of the target organisms if applicable,

11. anticipated mechanism and result of interaction between the released GMOs and the target organism(s) if applicable,

12. identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction,

13. likelihood of postrelease shifts in biological interactions or in host range,

14. known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens,

15. known or predicted involvement in biogeochemical processes,

16. other potential interactions with the environment.

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. **Monitoring techniques**

1. methods for tracing the GMOs, and for monitoring their effects,
2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques,
3. techniques for detecting transfer of the donated genetic material to other organisms,
4. duration and frequency of the monitoring.

B. **Control of the release**

1. methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of release or the designated area for use,
2. methods and procedures to protect the site from intrusion by unauthorised individuals,
3. methods and procedures to prevent other organisms from entering the site.

C. **Waste treatment**

1. type of waste generated,
2. expected amount of waste,
3. description of treatment envisaged.

D. **Emergency response plans**

1. methods and procedures for controlling the GMOs in case of unexpected spread,
2. methods for decontamination of the areas affected, for example eradication of the GMOs,
3. methods for disposal or sanitation of plants, animals, soils, etc., that were exposed during or after the spread,
4. methods for the isolation of the area affected by the spread,

5 plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

ANNEX III B

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

A. GENERAL INFORMATION

1. Name and address of the notifier (company or institute),
2. Name, qualifications and experience of the responsible scientist(s),
3. Title of the project,

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name:
   (a) family name
   (b) genus
   (c) species
   (d) subspecies
   (e) cultivar/breeding line
   (f) common name.
2. (a) Information concerning reproduction:
      (i) mode(s) of reproduction
      (ii) specific factors affecting reproduction, if any
      (iii) generation time.
   (b) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.
3. Survivability:
   (a) ability to form structures for survival or dormancy
   (b) specific factors affecting survivability, if any.
4. Dissemination:
   (a) ways and extent (for example an estimation of how viable pollen and/or seeds declines with distance) of dissemination
   (b) specific factors affecting dissemination, if any.
5. Geographical distribution of the plant.
6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
7. Other potential interactions, relevant to the GMO, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification.
2. Nature and source of the vector used.
3. Size, source (name) of donor organism(s) and intended function of each constituent fragment of the region intended for insertion.

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.

2. Information on the sequences actually inserted/deleted:

   (a) size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;

   (b) in case of deletion, size and function of the deleted region(s);

   (c) copy number of the insert;

   (d) location(s) of the insert(s) in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination.

3. Information on the expression of the insert:

   (a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation;

   (b) parts of the plant where the insert is expressed (for example roots, stem, pollen, etc.).

4. Information on how the genetically modified plant differs from the recipient plant in:

   (a) mode(s) and/or rate of reproduction;

   (b) dissemination;

   (c) survivability.

5. Genetic stability of the insert and phenotypic stability of the GMHP.

6. Any change to the ability of the GMHP to transfer genetic material to other organisms.

7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs.

9. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).

10. Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification.

11. Potential interactions with the abiotic environment.

12. Description of detection and identification techniques for the genetically modified plant.

13. Information about previous releases of the genetically modified plant, if applicable.

E. INFORMATION RELATING TO THE SITE OF RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7)

1. Location and size of the release site(s).

2. Description of the release site ecosystem, including climate, flora and fauna.

3. Presence of sexually compatible wild relatives or cultivated plant species.

4. Proximity to officially recognised biotopes or protected areas which may be affected.

F. INFORMATION RELATING TO THE RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7)

1. Purpose of the release.

2. Foreseen date(s) and duration of the release.

3. Method by which the genetically modified plants will be released.

4. Method for preparing and managing the release site, prior to, during and postrelease, including cultivation practices and harvesting methods.

5. Approximate number of plants (or plants per m^2).

G. INFORMATION ON CONTROL, MONITORING, POSTRELEASE AND WASTE TREATMENT PLANS (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7)

1. Any precautions taken:

   (a) distance(s) from sexually compatible plant species, both wild relatives and crops

   (b) any measures to minimise/prevent dispersal of any reproductive organ of the GMHP (for example pollen, seeds, tuber).

2. Description of methods for postrelease treatment of the site.

3. Description of postrelease treatment methods for the genetically modified plant material including wastes.

4. Description of monitoring plans and techniques.

5. Description of any emergency plans.

6. Methods and procedures to protect the site.

ANNEX IV

ADDITIONAL INFORMATION

This Annex describes in general terms the additional information to be provided in the case of notification for placing on the market and information for labelling requirements regarding GMOs as or in product to be placed on the market, and GMO exempted under Article 2(4), second subparagraph. It will be supplemented by guidance notes, as regards i.a. the description of how the product is intended to be used, to be developed in accordance with the procedure laid down in Article 30(2). The labelling of exempted organisms as required by Article 26 shall be met by providing appropriate recommendations for, and restrictions on, use:

A. The following information shall be provided in the notification for placing on the market of GMOs as or in product in addition to that of Annex III:

1. proposed commercial names of the products and names of GMOs contained therein, and any specific identification, name or code used by the notifier to identify the GMO. After the consent any new commercial names should be provided to the competent authority,

2. name and full address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor,

3. name and full address of the supplier(s) of control samples,

4. description of how the product and the GMO as or in product are intended to be used. Differences in use or management of the GMO compared to similar non-genetically modified products should be highlighted,

5. description of the geographical area(s) and types of environment where the product is intended to be used within the Community, including, where possible, estimated scale of use in each area,

6. intended categories of users of the product e.g. industry, agriculture and skilled trades, consumer use by public at large,

7. information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular GMO products to facilitate post-marketing control and inspection. This information should include where appropriate the lodging of samples of the GMO or its genetic material, with the competent authority and details of nucleotide sequences or other type of information which is necessary to identify the GMO product and its progeny, for example the methodology for detecting and identifying the GMO product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified,

8. proposed labelling on a label or in an accompanying document. This must include, at least in summarised form, a commercial name of the product, a statement that 'This product contains genetically modified organisms', the name of the GMO and the information referred to in point 2, the labelling should indicate how to access the information in the publicly accessible part of the register.

B. The following information shall be provided in the notification, when relevant, in addition to that of point A, in accordance with Article 13 of this Directive:

1. measures to take in case of unintended release or misuse,

2. specific instructions or recommendations for storage and handling,

3. specific instructions for carrying out monitoring and reporting to the notifier and, if required, the competent authority, so that the competent authorities can be effectively informed of any adverse effect. These instructions should be consistent with Annex VII part C,

4. proposed restrictions in the approved use of the GMO, for example where the product may be used and for what purposes,

5. proposed packaging,

6. estimated production in and/or imports to the Community,

7. proposed additional labelling. This may include, at least in summarised form, the information referred to in points A 4, A 5, B 1, B 2, B 3 and B 4.

ANNEX V

CRITERIA FOR THE APPLICATION OF DIFFERENTIATED PROCEDURES (ARTICLE 7)

The criteria referred to in Article 7(1) are set out below.

1. The taxonomic status and the biology (for example mode of reproduction and pollination, ability to cross with related species, pathogenecity) of the non-modified (recipient) organism shall be well-known.

2. There shall be sufficient knowledge about the safety for human health and the environment of the parental, where appropriate, and recipient organisms in the environment of the release.

3. Information shall be available on any interaction of particular relevance for the risk assessment, involving the parental, where appropriate, and recipient organism and other organisms in the experimental release ecosystem.

4. Information shall be available to demonstrate that any inserted genetic material is well characterised. Information on the construction of any vector systems or sequences of genetic material used with the carrier DNA shall be available. Where a genetic modification involves the deletion of genetic material, the extent of the deletion shall be known. Sufficient information on the genetic modification shall also be available to enable identification of the GMO and its progeny during a release.

5. The GMO shall not present additional or increased risks to human health or the environment under the conditions of the experimental release that are not presented by releases of the corresponding parental, where appropriate, and recipient organisms. Any capacity to spread in the environment and invade other unrelated ecosystems and capacity to transfer genetic material to other organisms in the environment shall not result in adverse effects.

ANNEX VI

GUIDELINES FOR THE ASSESSMENT REPORTS

The assessment report provided for by Articles 13, 17, 19 and 20 should include in particular the following:

1. Identification of the characteristics of the recipient organism which are relevant to the assessment of the GMO(s) in question. Identification of any known risks to human health and the environment resulting from the release into the environment of the recipient non-modified organism.

2. Description of the result of the genetic modification in the modified organism.

3. Assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment.

4. Identification of any new risks to human health and the environment that may arise from the release of the GMO(s) in question as compared to the release of the corresponding non-modified organism(s), based on the environmental risk assessment carried out in accordance with Annex II.

5. A conclusion on whether the GMO(s) in question should be placed on the market or as (a) product(s) and under which conditions, whether the GMOs in question shall not be placed on the market or whether the views of other competent authorities and the Commission are sought for on specific issues of the e.r.a.. These aspects should be specified. The conclusion should clearly address the use proposed, risk management and the monitoring plan proposed. In the case that it has been concluded that the GMOs should not be placed on the market, the competent authority shall give reasons for its conclusion.

ANNEX VII

MONITORING PLAN

This Annex describes in general terms the objective to be achieved and the general principles to be followed to design the monitoring plan referred to in Articles 13(2), 19(3) and 20. It will be supplemented by guidance notes to be developed in accordance with the procedure laid down in Article 30(2).

These guidance notes shall be completed by 17 October 2002.

A. **Objective**

The objective of a monitoring plan is to:

— confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the e.r.a. are correct, and

— identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the e.r.a.

B. **General principles**

Monitoring, as referred to in Articles 13, 19 and 20, takes place after the consent to the placing of a GMO on the market.

The interpretation of the data collected by monitoring should be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment should be considered to establish whether they are a consequence of the GMO or its use, as such changes may be the result of environmental factors other than the placing of the GMO on the market.

Experience and data gained through the monitoring of experimental releases of GMOs may assist in designing the post marketing monitoring regime required for the placing on the market of GMOs as or in products.

C. **Design of the monitoring plan**

The design of the monitoring plan should:

1. be detailed on a case by case basis taking into account the e.r.a.,

2. take into account the characteristics of the GMO, the characteristics and scale of its intended use and the range of relevant environmental conditions where the GMO is expected to be released,

3. incorporate general surveillance for unanticipated adverse effects and, if necessary, (case-) specific monitoring focusing on adverse effects identified in the e.r.a.:

   3.1. whereas case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the e.r.a.,

   3.2. whereas surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder should be provided.

4. facilitate the observation, in a systematic manner, of the release of a GMO in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment.

5. identify who (notifier, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the competent authority will be informed on any observed adverse effects on human health and the environment. (Time points and intervals for reports on the results of the monitoring shall be indicated).

6. give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and environment and enable the consent holder or the competent authority, where appropriate, to take the measures necessary to protect human health and the environment.

ANNEX VIII

CORRELATION TABLE

Directive 90/220/EEC	This Directive
Article 1 (1)	Article 1
Article 1 (2)	Article 3 (2)
Article 2	Article 2
Article 3	Article 3 (1)
Article 4	Article 4
—	Article 5
Article 5	Article 6
Article 6 (1) to 4	
Article 6 (5)	Article 7
Article 6 (6)	Article 8
Article 7	Article 9
Article 8	Article 10
Article 9	Article 11
Article 10 (2)	Article 12
Article 11	Article 13
Article 12 (1) to (3) and (5)	Article 14
Article 13 (2)	Article 15 (3)
—	Article 15 (1), (2) and (4)
—	Article 16
—	Article 17
Article 13 (3) and (4)	Article 18
Article 13 (5) and (6)	Article 19 (1) and (4)
Article 12 (4)	Article 20 (3)
Article 14	Article 21
Article 15	Article 22
Article 16	Article 23
—	Article 24 (1)
Article 17	Article 24 (2)
Article 19	Article 25
—	Article 26
Article 20	Article 27
—	Article 28
—	Article 29
Article 21	Article 30
Article 22	Article 31 (1), (4) and (5)
Article 18 (2)	Article 31 (6)
Article 18 (3)	Article 31 (7)
—	Article 32
—	Article 33
Article 23	Article 34
—	Article 35
—	Article 36
—	Article 37
Article 24	Article 38
Annex I A	Annex I A
Annex I B	Annex I B
—	Annex II
Annex II	Annex III
Annex II A	Annex III A
Annex II B	Annex III B
Annex III	Annex IV
—	Annex V
—	Annex VI
—	Annex VII

ANNEX 2

I

(Acts whose publication is obligatory)

REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure referred to in Article 251 of the Treaty [4],

Whereas:

(1) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be ensured in the pursuit of Community policies.

(3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community.

(4) Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of genetically modified food and feed may hinder their free movement, creating conditions of unequal and unfair competition.

(5) An authorisation procedure involving Member States and the Commission has been established for genetically modified foods in Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [5]. This procedure should be streamlined and made more transparent.

(6) Regulation (EC) No 258/97 also provides for a notification procedure for novel foods which are substantially equivalent to existing foods. Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself. In order to ensure clarity, transparency and a harmonised framework for authorisation of genetically modified food, this notification procedure should be abandoned in respect of genetically modified foods.

(7) Feed consisting of or containing genetically modified organisms (GMOs) has so far been authorised, subject to the authorisation procedure provided by Council Directive 90/220/EEC of 23 April 1990 [6] and Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [7]; no authorisation procedure exists for feed produced from GMOs; a single, efficient and transparent Community authorisation procedure for feed consisting of, containing or produced from GMOs should be established.

(8) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.

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[1] OJ C 304 E, 30.10.2001, p. 221.
[2] OJ C 221, 17.9.2002, p. 114.
[3] OJ C 278, 14.11.2002, p. 31.
[4] Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 31), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.
[5] OJ L 43, 14.2.1997, p. 1.
[6] OJ L 117, 8.5.1990, p. 15. Directive repealed by Directive 2001/18/EC.
[7] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).

(9) The new authorisation procedures for genetically modified food and feed should include the new principles introduced in Directive 2001/18/EC. They should also make use of the new framework for risk assessment in matters of food safety set up by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety ([1]). Thus, genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority (Authority), of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation should be followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States.

(10) Experience has shown that authorisation should not be granted for a single use, when a product is likely to be used both for food and feed purposes; therefore such products should only be authorised when fulfilling authorisation criteria for both food and feed.

(11) Under this Regulation, authorisation may be granted either to a GMO to be used as a source material for production of food or feed and products for food and/or feed use which contain, consist of or are produced from it, or to foods or feed produced from a GMO. Thus, where a GMO used in the production of food and/or feed has been authorised under this Regulation, foods and/or feed containing, consisting of or produced from that GMO will not need an authorisation under this Regulation, but will be subject to the requirements referred to in the authorisation granted in respect of the GMO. Furthermore, foods covered by an authorisation granted under this Regulation will be exempted from the requirements of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, except where they fall under one or more of the categories referred to in Article 1(2)(a) of Regulation (EC) No 258/97 in respect of a characteristic which has not been considered for the purpose of the authorisation granted under this Regulation.

(12) Council Directive 89/107/EEC of 21 December 1988 on the approximation of laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ([2]) provides for authorisation of additives used in foodstuffs. In addition to this authorisation procedure, food additives containing, consisting of or produced from GMOs should fall also within the scope of this Regulation for the safety assessment of the genetic modification, while the final authorisation should be granted under the procedure referred to in Directive 89/107/EEC.

(13) Flavourings falling within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ([3]) which contain, consist of or are produced from GMOs should also fall within the scope of this Regulation for the safety assessment of the genetic modification.

(14) Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ([4]) provides for an approval procedure for feed materials produced using different technologies that may pose risk to human or animal health and the environment. These feed materials containing, consisting of or produced from GMOs should fall instead within the scope of this Regulation.

(15) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ([5]), provides for an authorisation procedure for placing on the market additives used in feedingstuffs. In addition to this authorisation procedure, feed additives containing, consisting of or produced from GMOs should also fall within the scope of this Regulation.

(16) This Regulation should cover food and feed produced 'from' a GMO but not food and feed 'with' a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore,

([1]) OJ L 31, 1.2.2002, p. 1.
([2]) OJ L 40, 11.2.1989, p. 27. Directive as amended by Directive 94/34/EC of the European Parliament and of the Council (OJ L 237, 10.9.1994, p. 1).
([3]) OJ L 184, 15.7.1988, p. 61. Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).
([4]) OJ L 213, 21.7.1982, p. 8. Directive as last amended by Directive 1999/20/EC (OJ L 80, 25.3.1999, p. 20).
([5]) OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.

(17) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information. In addition to other types of information to the public provided for in this Regulation, the labelling of products enables the consumer to make an informed choice and facilitates fairness of transactions between seller and purchaser.

(18) Article 2 of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ([1]) provides that labelling must not mislead the purchaser as to the characteristics of the foodstuff and among other things, in particular, as to its nature, identity, properties, composition, method of production and manufacturing.

(19) Additional requirements for the labelling of genetically modified foods are laid down in Regulation (EC) No 258/97, in Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication, on the labelling of certain foodstuffs produced from genetically modified organisms, of particulars other than those provided for in Directive 79/112/EEC ([2]) and in Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms ([3]).

(20) Harmonised labelling requirements should be laid down for genetically modified feed to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed, thereby enabling the user to make an informed choice.

(21) The labelling should include objective information to the effect that a food or feed consists of, contains or is produced from GMOs. Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers, facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production.

(22) In addition, the labelling should give information about any characteristic or property which renders a food or feed different from its conventional counterpart with respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications for certain sections of the population, as well as any characteristic or property which gives rise to ethical or religious concerns.

(23) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ([4]) ensures that relevant information concerning any genetic modification is available at each stage of the placing on the market of GMOs and food and feed produced therefrom and should thereby facilitate accurate labelling.

(24) Despite the fact that some operators avoid using genetically modified food and feed, such material may be present in minute traces in conventional food and feed as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing. In such cases, this food or feed should not be subject to the labelling requirements of this Regulation. In order to achieve this objective, a threshold should be established for the adventitious or technically unavoidable presence of genetically modified material in foods or feed, both when the marketing of such material is authorised in the Community and when this presence is tolerated by virtue of this Regulation.

(25) It is appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of genetically modified materials in a food or feed or in one of its components is higher than the set threshold, such presence should be indicated in accordance with this Regulation and that detailed provisions should be adopted for its implementation. The possibility of establishing lower thresholds, in particular for foods and feed containing or consisting of GMOs or in order to take into account advances in science and technology, should be provided for.

(26) It is indispensable that operators strive to avoid any accidental presence of genetically modified material not authorised under Community legislation in food or feed. However, in order to ensure the practicability and feasibility of this Regulation, a specific threshold, with the possibility of establishing lower levels in particular for

([1]) OJ L 109, 6.5.2000, p. 29. Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).
([2]) OJ L 159, 3.6.1998, p. 4. Regulation as amended by Commission Regulation (EC) No 49/2000 (OJ L 6, 11.1.2000, p. 13).
([3]) OJ L 6, 11.1.2000, p. 15.

([4]) See page 24 of this Official Journal.

GMOs sold directly to the final consumer, should be established as a transitional measure for minute traces in food or feed of this genetically modified material, where the presence of such material is adventitious or technically unavoidable and provided that all specific conditions set in this Regulation are met. Directive 2001/18/EC should be amended accordingly. The application of this measure should be reviewed in the context of the general review of the implementation of this Regulation.

(27) In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of the genetically modified food or feed.

(28) Operators should avoid the unintended presence of GMOs in other products. The Commission should gather information and develop on this basis guidelines on the coexistence of genetically modified, conventional and organic crops. Moreover, the Commission is invited to bring forward, as soon as possible, any further necessary proposal.

(29) The traceability and labelling of GMOs at all stages of placing on the market, including the possibility of establishing thresholds, is ensured by Directive 2001/18/EC and Regulation (EC) No 1830/2003.

(30) It is necessary to establish harmonised procedures for risk assessment and authorisation that are efficient, time-limited and transparent, and criteria for evaluation of the potential risks arising from genetically modified foods and feed.

(31) In order to ensure a harmonised scientific assessment of genetically modified foods and feed, such assessments should be carried out by the Authority. However, as specific acts or omissions on the part of the Authority under this Regulation could produce direct legal effects on applicants, it is appropriate to provide for the possibility of an administrative review of such acts or omissions.

(32) It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account.

(33) Where the application concerns products containing or consisting of a genetically modified organism, the applicant should have the choice of either supplying an authorisation for the deliberate release into the environment already obtained under part C of Directive 2001/18/EC, without prejudice to the conditions set by that authorisation, or of applying for the environmental risk assessment to be carried out at the same time as the safety assessment under this Regulation. In the latter case, it is necessary for the evaluation of the environmental risk to comply with the requirements referred to in Directive 2001/18/EC and for the national competent authorities designated by Member States for this purpose to be consulted by the Authority. In addition, it is appropriate to give the Authority the possibility of asking one of these competent authorities to carry out the environmental risk assessment. It is also appropriate, in accordance with Article 12(4) of Directive 2001/18/EC, for the national competent authorities designated under the said Directive in all cases concerning GMOs and food and/or feed containing or consisting of a GMO to be consulted by the Authority before it finalises the environmental risk assessment.

(34) In the case of GMOs to be used as seeds or other plant-propagating materials falling within the scope of this Regulation, the Authority should be under an obligation to delegate the environmental risk assessment to a national competent authority. Nonetheless, authorisations under this Regulation should be without prejudice to the provisions of Directives 68/193/EEC ([1]), 2002/53/EC ([2]) and 2002/55/EC ([3]), which provide in particular for the rules and the criteria for the acceptance of varieties and their official acceptance for inclusion in common catalogues; nor should they affect the provisions of Directives 66/401/EEC ([4]), 66/402/EEC ([5]), 68/193/EEC, 92/33/EEC ([6]), 92/34/EEC ([7]), 2002/54/EC ([8]), 2002/55/EC, 2002/56/EC ([9]) or 2002/57/EC ([10]) which regulate in particular the certification and the marketing of seeds and other plant-propagating materials.

([1]) OJ L 93, 17.4.1968, p. 15. Directive as last amended by Directive 2002/11/EC (OJ L 53, 23.2.2002, p. 20).
([2]) OJ L 193, 20.7.2002, p. 1.
([3]) OJ L 193, 20.7.2002, p. 33.
([4]) OJ 125, 11.7.1966, p. 2298/66. Directive as last amended by Directive 2001/64/EC (OJ L 234, 1.9.2001, p. 60).
([5]) OJ 125, 11.7.1966, p. 2309/66. Directive as last amended by Directive 2001/64/EC.
([6]) OJ L 157, 10.6.1992, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
([7]) OJ L 157, 10.6.1992, p. 10. Directive as last amended by Regulation (EC) No 806/2003.
([8]) OJ L 193, 20.7.2002, p. 12.
([9]) OJ L 193, 20.7.2002, p. 60. Directive amended by Commission Decision 2003/66/EC (OJ L 25, 30.1.2003, p. 42).
([10]) OJ L 193, 20.7.2002, p. 74. Directive amended by Commission Directive 2003/45/EC (OJ L 138, 5.6.2003, p. 40).

(35) It is necessary to introduce, where appropriate and on the basis of the conclusions of the risk assessment, post-market monitoring requirements for the use of genetically modified foods for human consumption and for the use of genetically modified feed for animal consumption. In the case of GMOs, a monitoring plan concerning environmental effects is compulsory under Directive 2001/18/EC.

(36) To facilitate controls on genetically modified food and feed, applicants for authorisation should propose appropriate methods for sampling, identification and detection, and deposit samples of the genetically modified food and feed with the Authority; methods of sampling and detection should be validated, where appropriate, by the Community reference laboratory.

(37) Technological progress and scientific developments should be taken into account when implementing this Regulation.

(38) Food and feed falling within the scope of this Regulation which have been lawfully placed on the Community market before the date of application of this Regulation should continue to be allowed on the market, subject to the transmission to the Commission by the operators of information concerning the risk assessment, methods for sampling, identification and detection as appropriate, including the transmission of samples of the food and feed and their control samples within six months after the date of application of this Regulation.

(39) A register of genetically modified food and feed authorised under this Regulation should be established, including product specific information, studies which demonstrate the safety of the product, including, where available, references to independent and peer-reviewed studies, and to methods for sampling, identification and detection. Non-confidential data should be made available to the public.

(40) In order to stimulate research and development into GMOs for food and/or feed use, it is appropriate to protect the investment made by innovators in gathering the information and data supporting an application under this Regulation. This protection should however be limited in time in order to avoid the unnecessary repetition of studies and trials which would be against the public interest.

(41) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1].

(42) Provision should be made for consultation of the European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997, or any other appropriate body established by the Commission, with a view to obtaining advice on ethical issues regarding the placing on the market of genetically modified food or feed. Such consultations should be without prejudice to the competence of Member States as regards ethical issues.

(43) In order to provide a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, requirements arising from this Regulation should apply in a non-discriminatory manner to products originating in the Community and imported from third countries, in accordance with the general principles referred to in Regulation (EC) No 178/2002. The content of this Regulation takes account of the international trade commitments of the European Communities and of the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity as regards importer obligations and notification.

(44) Certain instruments of Community law should be repealed and others amended as a result of this Regulation.

(45) The implementation of this Regulation should be reviewed in the light of experience gained in the short term, and the impact of the application of this Regulation on human and animal health, consumer protection, consumer information and the functioning of the internal market should be monitored by the Commission,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

OBJECTIVE AND DEFINITIONS

Article 1

Objective

The objective of this Regulation, in accordance with the general principles laid down in Regulation (EC) No 178/2002, is to:

(a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;

[1] OJ L 184, 17.7.1999, p. 23.

(b) lay down Community procedures for the authorisation and supervision of genetically modified food and feed;

(c) lay down provisions for the labelling of genetically modified food and feed.

Article 2

Definitions

For the purposes of this Regulation:

1. the definitions of 'food', 'feed', 'final consumer', 'food business' and 'feed business' given in Regulation (EC) No 178/2002 shall apply;

2. the definition of 'traceability', laid down in Regulation (EC) No 1830/2003;

3. 'operator' means the natural or legal person responsible for ensuring that the requirements of this Regulation are met within the food businesses or feed businesses under its control;

4. the definitions of 'organism', 'deliberate release' and 'environmental risk assessment' referred to in Directive 2001/18/EC shall apply;

5. 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;

6. 'genetically modified food' means food containing, consisting of or produced from GMOs;

7. 'genetically modified feed' means feed containing, consisting of or produced from GMOs;

8. 'genetically modified organism for food use' means a GMO that may be used as food or as a source material for the production of food;

9. 'genetically modified organism for feed use' means a GMO that may be used as feed or as a source material for the production of feed;

10. 'produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

11. 'control sample' means the GMO or its genetic material (positive sample) and the parental organism or its genetic material that has been used for the purpose of the genetic modification (negative sample);

12. 'conventional counterpart' means a similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use;

13. 'ingredient' means 'ingredient' as referred to in Article 6(4) of Directive 2000/13/EC;

14. 'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale, or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

15. 'pre-packaged food' means any single item for presentation as such consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

16. 'mass caterer' means 'mass caterer' as referred to in Article 1 of Directive 2000/13/EC.

CHAPTER II

GENETICALLY MODIFIED FOOD

Section 1

Authorisation and supervision

Article 3

Scope

1. This Section shall apply to:

(a) GMOs for food use;

(b) food containing or consisting of GMOs;

(c) food produced from or containing ingredients produced from GMOs.

2. Where necessary, it may be determined in accordance with the procedure referred to in Article 35(2) whether a type of food falls within the scope of this Section.

Article 4

Requirements

1. Food referred to in Article 3(1) must not:

(a) have adverse effects on human health, animal health or the environment;

(b) mislead the consumer;

(c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

2. No person shall place on the market a GMO for food use or food referred to in Article 3(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.

3. No GMO for food use or food referred to in Article 3(1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article.

4. The authorisation referred to in paragraph 2 may cover:

(a) a GMO and foods containing or consisting of that GMO as well as foods produced from or containing ingredients produced from that GMO; or

(b) food produced from a GMO as well as foods produced from or containing that food;

(c) an ingredient produced from a GMO as well as food containing that ingredient.

5. An authorisation as referred to in paragraph 2 shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation.

6. The applicant for an authorisation as referred to in paragraph 2 and, after the authorisation is granted, the authorisation-holder or his representative, shall be established in the Community.

7. Authorisation under this Regulation shall be without prejudice to Directive 2002/53/EC, Directive 2002/55/EC and Directive 68/193/EEC.

Article 5

Application for authorisation

1. To obtain the authorisation referred to in Article 4(2), an application shall be submitted in accordance with the following provisions.

2. The application shall be sent to the national competent authority of a Member State.

(a) The national competent authority:

(i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) shall inform without delay the European Food Safety Authority (hereinafter referred to as the Authority); and

(iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.

(b) The Authority

(i) shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;

(ii) shall make the summary of the dossier referred to in paragraph 3(1) available to the public.

3. The application shall be accompanied by the following:

(a) the name and the address of the applicant;

(b) the designation of the food, and its specification, including the transformation event(s) used;

(c) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as the Cartagena Protocol);

(d) where applicable, a detailed description of the method of production and manufacturing;

(e) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the food complies with the criteria referred to in Article 4(1);

(f) either an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in Article 13(2)(a), or a proposal for labelling the food in accordance with Article 13(2)(a) and (3);

(g) either a reasoned statement that the food does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 13(2)(b);

(h) where appropriate, the conditions for placing on the market the food or foods produced from it, including specific conditions for use and handling;

(i) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it;

(j) samples of the food and their control samples, and information as to the place where the reference material can be accessed;

(k) where appropriate, a proposal for post-market monitoring regarding use of the food for human consumption;

(l) a summary of the dossier in a standardised form.

4. In the case of an application relating to a GMO for food use, references to 'food' in paragraph 3 shall be interpreted as referring to food containing, consisting of or produced from the GMO in respect of which an application is made.

5. In the case of GMOs or food containing or consisting of GMOs, the application shall also be accompanied by:

(a) the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMO has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision;

(b) a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.

In such case, Articles 13 to 24 of Directive 2001/18/EC shall not apply.

6. Where the application concerns a substance, the use and placing on the market of which is subject, under other provisions of Community law, to its inclusion on a list of substances registered or authorised to the exclusion of others, this must be stated in the application and the status of the substance under the relevant legislation must be indicated.

7. The Commission, having first consulted the Authority, shall establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

8. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of the application.

Article 6

Opinion of the Authority

1. In giving its opinion, the Authority shall endeavour to respect a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided for in paragraph 2.

2. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

3. In order to prepare its opinion the Authority:

(a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 5 and examine whether the food complies with the criteria referred to in Article 4(1);

(b) may ask the appropriate food assessment body of a Member State to carry out a safety assessment of the food in accordance with Article 36 of Regulation (EC) No 178/2002;

(c) may ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out an environmental risk assessment; however, if the application concerns GMOs to be used as seeds or other plant-propagating material, the Authority shall ask a national competent authority to carry out the environmental risk assessment;

(d) shall forward to the Community reference laboratory referred to in Article 32 the particulars referred to in Article 5(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant;

(e) shall, in verifying the application of Article 13(2)(a), examine the information and data submitted by the applicant to show that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.

4. In the case of GMOs or food containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs. During evaluation of requests for the placing on the market of products consisting of or containing GMOs, the national competent authority within the meaning of Directive 2001/18/EC designated by each Member State for this purpose shall be consulted by the Authority. The competent authorities shall have three months after the date of receiving the request within which to make their opinion known.

5. In the event of an opinion in favour of authorising the food, the opinion shall also include the following particulars:

(a) the name and address of the applicant;

(b) the designation of the food, and its specification;

(c) where applicable, the information required under Annex II to the Cartagena Protocol;

(d) the proposal for the labelling of the food and/or foods produced from it;

(e) where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas;

(f) the method, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it; an indication of where appropriate reference material can be accessed;

(g) where appropriate, the monitoring plan referred to in Article 5(5)(b).

6. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the food and stating the reasons for its opinion and the information on which this opinion is based, including the opinions of the competent authorities when consulted in accordance with paragraph 4.

7. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

Article 7

Authorisation

1. Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

2. Any draft decision which envisages the granting of authorisation shall include the particulars referred to in Article 6(5), the name of the authorisation-holder and, where appropriate, the unique identifier attributed to the GMO as referred to in the Regulation (EC) No 1830/2003.

3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 35(2).

4. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

5. The authorisation granted in accordance with the procedure referred to in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 11. The authorised food shall be entered in the Register referred to in Article 28. Each entry in the Register shall mention the date of authorisation and shall include the particulars referred to in paragraph 2.

6. The authorisation under this Section shall be without prejudice to other provisions of Community law governing the use and placing on the market of substances which may only be used if they are included in a list of substances registered or authorised to the exclusion of others.

7. The granting of authorisation shall not lessen the general civil and criminal liability of any food operator in respect of the food concerned.

8. References made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive shall be considered as applying equally to GMOs authorised under this Regulation.

Article 8

Status of existing products

1. By way of derogation from Article 4(2), products falling within the scope of this Section which have been lawfully placed on the market in the Community before the date of application of this Regulation may continue to be placed on the market, used and processed provided that the following conditions are met:

(a) in the case of products placed on the market under Directive 90/220/EEC before the entry into force of Regulation (EC) No 258/97 or in accordance with the provisions referred to in Regulation (EC) No 258/97, operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission of the date on which they were first placed on the market in the Community;

(b) in the case of products which have been lawfully placed on the market in the Community but are not covered by point (a), operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission that the products were placed on the market in the Community before the date of application of this Regulation.

2. The notification referred to in paragraph 1 shall be accompanied by the particulars mentioned in Article 5(3) and (5), as appropriate, which the Commission shall forward to the Authority and the Member States. The Authority shall forward to the Community reference laboratory the particulars referred to in Article 5(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant.

3. Within one year from the date of application of this Regulation and after verification that all the information required has been submitted and examined, the products concerned shall be entered in the Register. Each entry in the Register shall include the particulars referred to in Article 7(2) as appropriate and, in the case of the products referred to in paragraph 1(a), shall mention the date on which the products concerned were first placed on the market.

4. Within nine years from the date on which the products referred to in paragraph 1(a) were first placed on the market, but in no case earlier than three years after the date of application of this Regulation, operators responsible for placing them on the market shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

Within three years from the date of application of this Regulation, operators responsible for placing on the market products referred to in paragraph 1(b) shall submit an application in accordance with Article 11, which shall apply *mutatis mutandis*.

5. Products referred to in paragraph 1 and food containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 9, 10 and 34, which shall apply *mutatis mutandis*.

6. Where the notification and accompanying particulars referred to in paragraphs 1 and 2 are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 4 within the period specified, the Commission, acting in accordance with the procedure referred to in Article 35(2), shall adopt a measure requiring the product concerned and any products derived from it to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

7. In the case of authorisations not issued to a specific holder, the operator who imports, produces or manufactures the products referred to in this Article shall submit the information or the application to Commission.

8. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

Article 9

Supervision

1. After an authorisation has been issued in accordance with this Regulation, the authorisation-holder and parties concerned shall comply with any conditions or restrictions which have been imposed in the authorisation and shall in particular make sure that products not covered by the authorisation are not placed on the market as food or feed. Where post-market monitoring as referred to in Article 5(3)(k) and/or monitoring as referred to in Article 5(5)(b) has been imposed on the authorisation-holder, the authorisation-holder shall ensure that it is carried out and shall submit reports to the Commission in accordance with the terms of the authorisation. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30.

2. If the authorisation-holder proposes to modify the terms of the authorisation, the authorisation-holder shall submit an application in accordance with Article 5(2). Articles 5, 6 and 7 shall apply *mutatis mutandis*.

3. The authorisation-holder shall forthwith inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the food. In particular, the authorisation-holder shall forthwith inform the Commission of any prohibition or restriction imposed by the competent authority of any third country in which the food is placed on the market.

4. The Commission shall make the information supplied by the applicant available to the Authority and the Member States without delay.

Article 10

Modification, suspension and revocation of authorisations

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 3(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

2. The Commission shall examine the opinion of the Authority as soon as possible. Any appropriate measures shall be taken in accordance with Article 34. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure referred to in Article 7.

3. Articles 5(2), 6 and 7 shall apply *mutatis mutandis*.

Article 11

Renewal of authorisations

1. Authorisations under this Regulation shall be renewable for 10-year periods, on application to the Commission by the authorisation-holder at the latest one year before the expiry date of the authorisation.

2. The application shall be accompanied by the following:

(a) a copy of the authorisation for placing the food on the market;

(b) a report on the results of the monitoring, if so specified in the authorisation;

(c) any other new information which has become available with regard to the evaluation of the safety in use of the food and the risks of the food to the consumer or the environment;

(d) where appropriate, a proposal for amending or complementing the conditions of the original authorisation, *inter alia* the conditions concerning future monitoring.

3. Articles 5(2), 6 and 7 shall apply *mutatis mutandis*.

4. Where, for reasons beyond the control of the authorisation-holder, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until a decision is taken.

5. The Commission, having first consulted the Authority, may establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

6. The Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

Section 2

Labelling

Article 12

Scope

1. This Section shall apply to foods which are to be delivered as such to the final consumer or mass caterers in the Community and which:

(a) contain or consist of GMOs; or

(b) are produced from or contain ingredients produced from GMOs.

2. This Section shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

3. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.

4. Appropriate lower thresholds may be established in accordance with the procedure referred to in Article 35(2) in particular in respect of foods containing or consisting of GMOs or in order to take into account advances in science and technology.

Article 13

Requirements

1. Without prejudice to the other requirements of Community law concerning the labelling of foodstuffs, foods falling within the scope of this Section shall be subject to the following specific labelling requirements:

(a) where the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified (name of the ingredient)' shall appear in the list of ingredients provided for in Article 6 of Directive 2000/13/EC in parentheses immediately following the ingredient concerned;

(b) where the ingredient is designated by the name of a category, the words 'contains genetically modified (name of organism)' or 'contains (name of ingredient) produced from genetically modified (name of organism)' shall appear in the list of ingredients;

(c) where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified (name of organism)' shall appear clearly on the labelling;

(d) the indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they shall appear clearly on the labelling;

(e) where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm^2, the information required under this paragraph must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

2. In addition to the labelling requirements referred to in paragraph 1, the labelling shall also mention any characteristic or property, as specified in the authorisation, in the following cases:

(a) where a food is different from its conventional counterpart as regards the following characteristics or properties:

(i) composition;

(ii) nutritional value or nutritional effects;

(iii) intended use of the food;

(iv) implications for the health of certain sections of the population;

(b) where a food may give rise to ethical or religious concerns.

3. In addition to the labelling requirements referred to in paragraph 1 and as specified in the authorisation, the labelling of foods falling within the scope of this Section which do not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the foods concerned.

Article 14

Implementing measures

1. Detailed rules for implementing this Section, amongst other things regarding the measures necessary for operators to comply with the labelling requirements, may be adopted in accordance with the procedure referred to in Article 35(2).

2. Specific rules concerning the information to be given by mass caterers providing food to the final consumer may be adopted in accordance with the procedure referred to in Article 35(2).

In order to take into account the specific situation of mass caterers, such rules may provide for adaptation of the requirements of Article 13(1)(e).

CHAPTER III

GENETICALLY MODIFIED FEED

Section 1

Authorisation and supervision

Article 15

Scope

1. This Section shall apply to:

(a) GMOs for feed use;

(b) feed containing or consisting of GMOs;

(c) feed produced from GMOs.

2. Where necessary, it may be determined in accordance with the procedure referred to in Article 35(2) whether a type of feed falls within the scope of this Section.

Article 16

Requirements

1. Feed referred to in Article 15(1) must not:

(a) have adverse effects on human health, animal health or the environment;

(b) mislead the user;

(c) harm or mislead the consumer by impairing the distinctive features of the animal products;

(d) differ from feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans.

2. No person shall place on the market, use or process a product referred to in Article 15(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.

3. No product referred to in Article 15(1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article.

4. The authorisation referred to in paragraph 2 may cover:

(a) a GMO and feed containing or consisting of that GMO as well as feed produced from that GMO; or

(b) feed produced from a GMO as well as feeds produced from or containing that feed.

5. An authorisation as referred to in paragraph 2 shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation.

6. The applicant for an authorisation as referred to in paragraph 2 and, after the authorisation is granted, the authorisation-holder or his representative, shall be established in the Community.

7. Authorisation under this Regulation shall be without prejudice to Directive 2002/53/EC, Directive 2002/55/EC and Directive 68/193/EEC.

Article 17

Application for authorisation

1. To obtain the authorisation referred to in Article 16(2), an application shall be submitted in accordance with the following provisions.

2. The application shall be sent to the national competent authority of a Member State.

(a) The national competent authority:

(i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) shall inform the Authority without delay; and

(iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.

(b) The Authority:

(i) shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;

(ii) shall make the summary of the dossier referred to in paragraph 3(1) available to the public.

3. The application shall be accompanied by the following:

(a) the name and the address of the applicant;

(b) the designation of the feed and its specification, including the transformation event(s) used;

(c) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol;

(d) where applicable, a detailed description of the method of production and manufacturing and intended uses of the feed;

(e) a copy of the studies including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the feed complies with the criteria referred to in Article 16(1), and, in particular for feed falling within the scope of Directive 82/471/EEC, the information required under Council Directive 83/228/EEC of 18 April 1983 on the fixing of guidelines for the assessment of certain products used in animal nutrition [1];

(f) either an analysis, supported by appropriate information and data, showing that the characteristics of the feed are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in Article 25(2)(c), or a proposal for labelling the feed in accordance with Article 25(2)(c) and (3);

(g) either a reasoned statement that the feed does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 25(2)(d);

(h) where appropriate, the conditions for placing the feed on the market, including specific conditions for use and handling;

(i) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed and/or in the feed produced from it;

(j) samples of the feed and their control samples and information as to the place where the reference material can be accessed;

(k) where appropriate, a proposal for post-market monitoring for the use of the feed for animal consumption;

(l) a summary of the dossier in a standardised form.

4. In the case of an application relating to a GMO for feed use, references to 'feed' in paragraph 3 shall be interpreted as referring to feed containing, consisting of or produced from the GMO in respect of which an application is made.

5. In the case of GMOs or feed containing or consisting of GMOs, the application shall also be accompanied by:

(a) the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMOs has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision;

(b) a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.

In such case, Articles 13 to 24 of Directive 2001/18/EC shall not apply.

6. Where the application concerns a substance, the use and placing on the market of which is subject under other provisions of Community law to its inclusion on a list of substances registered or authorised to the exclusion of others, this must be stated in the application and the status of the substance under the relevant legislation must be indicated.

7. The Commission, having first consulted the Authority, shall establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

8. Before the date of application of this Regulation, the Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of the application.

[1] OJ L 126, 13.5.1983, p. 23.

Article 18

Opinion of the Authority

1. In giving its opinion, the Authority shall endeavour to comply with a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided in paragraph 2.

2. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

3. In order to prepare its opinion, the Authority:

(a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 17, and examine whether the feed complies with the criteria laid down in Article 16(1);

(b) may ask the appropriate feed assessment body of a Member State to carry out a safety assessment of the feed in accordance with Article 36 of Regulation (EC) No 178/2002;

(c) may ask a competent authority designated in accordance with Article 4 of Directive 2001/18/EC to carry out an environmental risk assessment; however, if the application concerns GMOs to be used as seeds or other plant-propagating material, the Authority shall ask a national competent authority to carry out the environmental risk assessment;

(d) shall forward to the Community reference laboratory the particulars referred to in Article 17(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant;

(e) shall, in verifying the application of Article 25(2)(c), examine the information and data submitted by the applicant to show that the characteristics of the feed are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics.

4. In the case of GMOs or feed containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs. During evaluation of requests for the placing on the market of products consisting of or containing GMOs, the national competent authority within the meaning of Directive 2001/18/EC, designated by each Member State for this purpose shall be consulted by the Authority. The competent authorities shall have three months after the date of receiving the request within which to make their opinion known.

5. In the event of an opinion in favour of authorising the feed, the opinion shall also include the following particulars:

(a) the name and address of the applicant;

(b) the designation of the feed, and its specification;

(c) where applicable, the information required under Annex II to the Cartagena Protocol;

(d) the proposal for the labelling of the feed;

(e) where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas;

(f) the method, validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed and/or in feed produced from it; an indication of where appropriate reference material can be accessed;

(g) where appropriate, the monitoring plan as referred to in Article 17(5)(b).

6. The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the feed and stating the reasons for its opinion and the information on which this opinion is based, including the opinions of the competent authorities when consulted in accordance with paragraph 4.

7. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

Article 19

Authorisation

1. Within three months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred in Article 35 a draft of the decision to be taken in respect of the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

2. Any draft decision which envisages the granting of authorisation shall include the particulars referred to in Article 18(5), the name of the authorisation-holder and, where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No 1830/2003.

3. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 35(2).

4. The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

5. The authorisation granted in accordance with the procedure referred to in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 23. The authorised feed shall be entered in the Register referred to in Article 28. Each entry in the Register shall mention the date of authorisation and shall include the particulars referred to in paragraph 2.

6. The authorisation under this Section shall be without prejudice to other provisions of Community law governing the use and placing on the market of substances which may only be used if they are included in a list of substances registered or authorised to the exclusion of others.

7. The granting of authorisation shall not lessen the general civil and criminal liability of any feed operator in respect of the feed concerned.

8. References made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive shall be considered as applying equally to GMOs authorised under this Regulation.

Article 20

Status of existing products

1. By way of derogation from Article 16(2), products falling within the scope of this Section which have been lawfully placed on the market in the Community before the date of application of this Regulation may continue to be placed on the market, used and processed provided that the following conditions are met:

(a) in the case of products which have been authorised under Directives 90/220/EEC or 2001/18/EC, including use as feed, under Directive 82/471/EEC, which are produced from GMOs, or under Directive 70/524/EEC, which contain, consist of or are produced from GMOs, operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission of the date on which they were first placed on the market in the Community;

(b) in the case of products which have been lawfully placed on the market in the Community but which are not referred to in point (a), operators responsible for placing on the market in the Community the products concerned shall, within six months after the date of application of this Regulation, notify the Commission that the products were placed on the market in the Community before the date of application of this Regulation.

2. The notification referred to in paragraph 1 shall be accompanied by the particulars mentioned in Article 17(3) and (5), as appropriate, which the Commission shall forward to the Authority and the Member States. The Authority shall forward to the Community reference laboratory the particulars referred to in Article 17(3)(i) and (j). The Community reference laboratory shall test and validate the method of detection and identification proposed by the applicant.

3. Within one year from the date of application of this Regulation and after verification that all the information required has been submitted and examined, the products concerned shall be entered in the Register. Each entry in the Register shall include the particulars referred to in Article 19(2) as appropriate and, in the case of the products referred to in paragraph 1(a), shall mention the date on which the products concerned were first placed on the market.

4. Within nine years from the date on which the products referred to in paragraph 1(a) were first placed on the market, but in no case earlier than three years after the date of application of this Regulation, operators responsible for placing them on the market shall submit an application in accordance with Article 23, which shall apply *mutatis mutandis*.

Within three years from the date of application of this Regulation, operators responsible for placing on the market products referred to in paragraph 1(b) shall submit an application in accordance with Article 23, which shall apply *mutatis mutandis*.

5. Products referred to in paragraph 1 and feed containing them or produced from them shall be subject to the provisions of this Regulation, in particular Articles 21, 22 and 34, which shall apply *mutatis mutandis*.

6. Where the notification and accompanying particulars referred to in paragraphs 1 and 2 are not supplied within the period specified or are found to be incorrect, or where an application is not submitted as required by paragraph 4 within the period specified, the Commission, acting in accordance with the procedure laid down in Article 35(2), shall adopt a measure requiring the product concerned and any products derived from it to be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up.

7. In the case of authorisations not issued to a specific holder, the operator who imports, produces or manufactures the products referred to in this Article shall submit the information or the application to the Commission.

8. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

Article 21

Supervision

1. After an authorisation has been issued in accordance with this Regulation, the authorisation-holder and the parties concerned shall comply with any conditions or restrictions which have been imposed in the authorisation and shall in particular make sure that products not covered by the authorisation are not placed on the market as food or feed. Where post-market monitoring as referred to in Article 17(3)(k) and/or monitoring as referred to in Article 17(5)(b) has been imposed on the authorisation-holder, the authorisation-holder shall ensure that it is carried out and shall submit reports to the Commission in accordance with the terms of the authorisation. The monitoring reports referred to shall be made accessible to the public after deletion of any information identified as confidential in accordance with Article 30.

2. If the authorisation-holder proposes to modify the terms of the authorisation, the authorisation-holder shall submit an application in accordance with Article 17(2). Articles 17, 18 and 19 shall apply *mutatis mutandis*.

3. The authorisation-holder shall forthwith inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the feed. In particular, the authorisation-holder shall forthwith inform the Commission of any prohibition or restriction imposed by the competent Authority of any third country in which the feed is placed on the market.

4. The Commission shall make the information supplied by the applicant available to the Authority and the Member States without delay.

Article 22

Modification, suspension and revocation of authorisations

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 15(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.

2. The Commission shall examine the opinion of the Authority as soon as possible. Any appropriate measures shall be taken in accordance with Article 34. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedure referred to in Article 19.

3. Articles 17(2), 18 and 19 shall apply *mutatis mutandis*.

Article 23

Renewal of authorisations

1. Authorisations under this Regulation shall be renewable for 10-year periods, on application to the Commission by the authorisation-holder at the latest one year before the expiry date of the authorisation.

2. The application shall be accompanied by the following particulars and documents:

(a) a copy of the authorisation for placing the feed on the market;

(b) a report on the results of the monitoring, if so specified in the authorisation;

(c) any other new information which has become available with regard to the evaluation of the safety in use of the feed and the risks of the feed to animals, humans or the environment;

(d) where appropriate, a proposal for amending or complementing the conditions of the original authorisation, *inter alia* the conditions concerning future monitoring.

3. Articles 17(2), 18 and 19 shall apply *mutatis mutandis*.

4. Where, for reasons beyond the control of the authorisation-holder, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until a decision is taken.

5. The Commission, having first consulted the Authority, may establish, in accordance with the procedure referred to in Article 35(2), implementing rules for the application of this Article, including rules concerning the preparation and the presentation of the application.

6. The Authority shall publish detailed guidance to assist the applicant in the preparation and the presentation of its application.

Section 2

Labelling

Article 24

Scope

1. This Section shall apply to feed referred to in Article 15(1).

2. This Section shall not apply to feed containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the feed and of each feed of which it is composed, provided that this presence is adventitious or technically unavoidable.

3. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such materials.

4. Appropriate lower thresholds may be established in accordance with the procedure referred to in Article 35(2), in particular in respect of feed containing or consisting of GMOs, or in order to take into account advances in science and technology.

Article 25

Requirements

1. Without prejudice to the other requirements of Community law concerning the labelling of feed, feed referred to in Article 15(1) shall be subject to the specific labelling requirements laid down below.

2. No person shall place a feed referred to in Article 15(1) on the market unless the particulars specified below are shown, in a clearly visible, legible and indelible manner, on an accompanying document or, where appropriate, on the packaging, on the container or on a label attached thereto.

Each feed of which a particular feed is composed shall be subject to the following rules:

(a) for the feeds referred to in Article 15(1) (a) and (b), the words 'genetically modified (name of the organism)' shall appear in parentheses immediately following the specific name of the feed.

Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;

(b) for the feed referred to in Article 15(1)(c), the words 'produced from genetically modified (name of the organism)' shall appear in parentheses immediately following the specific name of the feed.

Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;

(c) as specified in the authorisation, any characteristic of the feed referred to in Article 15(1) such as those indicated hereunder, which is different from its conventional counterpart:

(i) composition;

(ii) nutritional properties;

(iii) intended use;

(iv) implications for the health of certain species or categories of animals;

(d) as specified in the authorisation, any characteristic or property where a feed may give rise to ethical or religious concerns.

3. In addition to the requirements referred to in paragraph 2(a) and (b) and as specified in the authorisation, the labelling or accompanying documents of feed falling within the scope of this Section which does not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the feed concerned.

Article 26

Implementing measures

Detailed rules for implementing this Section, amongst other things regarding the measures necessary for operators to comply with the labelling requirements, may be adopted in accordance with the procedure referred to in Article 35(2).

CHAPTER IV

COMMON PROVISIONS

Article 27

Products likely to be used as both food and feed

1. Where a product is likely to be used as both food and feed, a single application under Articles 5 and 17 shall be submitted and shall give rise to a single opinion from the Authority and a single Community decision.

2. The Authority shall consider whether the application for authorisation should be submitted both as food and feed.

Article 28

Community register

1. The Commission shall establish and maintain a Community register of genetically modified food and feed, hereinafter referred to as 'the Register'.

2. The Register shall be made available to the public.

Article 29

Public access

1. The application for authorisation, supplementary information from the applicant, opinions from the competent authorities designated in accordance with Article 4 of Directive 2001/18/EC, monitoring reports and information from the authorisation holder, excluding confidential information, shall be made accessible to the public.

2. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [1] when handling applications for access to documents held by the Authority.

3. Member States shall handle applications for access to documents received under this regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

Article 30

Confidentiality

1. The applicant may indicate which information submitted under this Regulation it wishes to be treated as confidential on the ground that its disclosure might significantly harm its competitive position. Verifiable justification must be given in such cases.

2. Without prejudice to paragraph 3, the Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant of its decision.

3. Information relating to the following shall not be considered confidential:

(a) name and composition of the GMO, food or feed referred to in Articles 3(1) and 15(1) and, where appropriate, indication of the substrate and the micro-organism;

(b) general description of the GMO and the name and address of the authorisation-holder;

(c) physico-chemical and biological characteristics of the GMO, food or feed referred to in Articles 3(1) and 15(1);

(d) effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on human and animal health and on the environment;

(e) effects of the GMO, food or feed referred to in Articles 3(1) and 15(1) on the characteristics of animal products and its nutritional properties;

(f) methods for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed referred to in Articles 3(1) and 15(1);

(g) information on waste treatment and emergency response.

4. Notwithstanding paragraph 2, the Authority shall on request supply the Commission and Member States with all information in its possession.

5. The use of the detection methods and the reproduction of the reference materials, provided under Article 5(3) and 17(3) for the purpose of applying this Regulation to the GMOs, food or feed to which an application refers, shall not be restricted by the exercise of intellectual property rights or otherwise.

6. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

7. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information, including research and development information, as well as information as to the confidentiality of which the Commission and the applicant disagree.

Article 31

Data protection

The scientific data and other information in the application dossier required under Article 5(3) and (5) and Article 17(3) and (5) may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the authorisation-holder that such data and information may be used.

On the expiry of this 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant if the applicant can demonstrate that the food or feed for which it is seeking authorisation is essentially similar to a food or feed already authorised under this Regulation.

Article 32

Community reference laboratory

The Community reference laboratory and its duties and tasks shall be those referred to in the Annex.

National reference laboratories may be established in accordance with the procedure referred to in Article 35(2).

Applicants for authorisation of genetically modified food and feed shall contribute to supporting the costs of the tasks of the Community reference laboratory and the European Network of GMO laboratories mentioned in the Annex.

[1] OJ L 145, 31.5.2001, p. 43.

The contributions from applicants shall not exceed the costs incurred in carrying out the validation of detection methods.

Detailed rules for implementing this Article, the Annex and any changes to it may be adopted in accordance with the procedure referred to in Article 35(2).

Article 33

Consultation with the European Group on Ethics in Science and New Technologies

1. The Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics in Science and New Technologies or any other appropriate body it might establish, with a view to obtaining its opinion on ethical issues.

2. The Commission shall make these opinions available to the public.

Article 34

Emergency measures

Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002.

Article 35

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002, hereinafter referred to as the 'Committee'.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 36

Administrative review

Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.

The Commission shall take a decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act.

Article 37

Repeals

The following Regulations shall be repealed with effect from the date of application of this Regulation:

— Regulation (EC) No 1139/98,

— Regulation (EC) No 49/2000,

— Regulation (EC) No 50/2000.

Article 38

Amendments to Regulation (EC) No 258/97

Regulation (EC) No 258/97 is hereby amended with effect from the date of application of this Regulation as follows:

1. The following provisions shall be deleted:
   — Article 1(2)(a) and (b),
   — Article 3(2), second subparagraph, and (3),
   — Article 8(1)(d),
   — Article 9.

2. In Article 3, the first sentence of paragraph 4 shall be replaced by the following:

   '4. By way of derogation from paragraph 2, the procedure referred to in Article 5 shall apply to foods or food ingredients referred to in Article 1(2)(d) and (e) which, on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies referred to in Article 4(3), are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.'

Article 39

Amendment to Directive 82/471/EEC

The following paragraph shall be added to Article 1 of Directive 82/471/EEC with effect from the date of application of this Regulation:

'3. This Directive does not apply to products which act as direct or indirect protein sources that fall within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*).

(*) OJ L 268, 18.10.2003, p. 1.'

Article 40

Amendments to Directive 2002/53/EC

Directive 2002/53/EC is hereby amended with effect from the date of application of this Regulation as follows:

1. Article 4(5) shall be replaced by the following:

'5. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or in feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*), the variety shall be accepted only if it has been approved in accordance with that Regulation.

(*) OJ L 268, 18.10.2003, p. 1.'

2. Article 7(5) shall be replaced by the following:

'5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety (*) is accepted only if it has been authorised under the relevant legislation.

(*) OJ L 31, 1.2.2002, p. 1.'

Article 41

Amendments to Directive 2002/55/EC

Directive 2002/55/EC is hereby amended with effect from the date of application of this Regulation as follows:

1. Article 4(3) shall be replaced by the following:

'3. Further, when material derived from a plant variety is intended to be used in food falling within the scope of Article 3, or in feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*), the variety shall be accepted only if it has been approved in accordance with that Regulation.

(*) OJ L 268, 18.10.2003, p. 1.'

2. Article 7(5) shall be replaced by the following:

'5. Member States shall ensure that a variety intended to be used in food or feed as defined in Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety (*) is accepted only if it has been authorised under the relevant legislation.

(*) OJ L 31, 1.2.2002, p. 1.'

Article 42

Amendment to Directive 68/193/EEC

Article 5ba(3) of Directive 68/193/EEC shall be replaced by the following wording with effect from the date of application of this Regulation:

'3. (a) Where products derived from vine-propagating material are intended to be used as or in food falling within the scope of Article 3 or as or in a feed falling within the scope of Article 15 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*), the vine variety concerned shall be accepted only if it has been authorised pursuant to the said Regulation.

(b) Member States shall ensure that a vine variety, from the propagating material of which products were derived intended for use in food and feed pursuant to Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety (**) shall be accepted only if it has been authorised pursuant to the relevant legislation.

(*) OJ L 268, 18.10.2003, p. 1.
(**) OJ L 31, 1.2.2002, p. 1.'

Article 43

Amendments to Directive 2001/18/EC

Directive 2001/18/EC is hereby amended with effect from the date of entry into force of this Regulation, as follows:

1. The following Article shall be inserted:

'*Article 12a*

Transitional measures for adventitious or technically unavoidable presence of genetically modified organisms having benefited from a favourable risk evaluation

1. Placing on the market of traces of a GMO or combination of GMOs in products intended for direct use as food or feed or for processing shall be exempted from Articles 13 to

21 provided that they meet the conditions referred to in Article 47 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (*).

2. This Article shall be applicable for a period of three years after the date of application of Regulation (EC) No 1829/2003.

(*) OJ L 268, 18.10.2003, p. 1.'

2. The following Article shall be inserted:

'*Article 26a*

Measures to avoid the unintended presence of GMOs

1. Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.

2. The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.'

Article 44

Information to be provided in accordance with the Cartagena Protocol

1. Any authorisation, renewal, modification, suspension or revocation of authorisation of a GMO, food or feed referred to in Articles 3(1)(a) or (b) or 15(1)(a) or (b) shall be notified by the Commission to the Parties to the Cartagena Protocol through the biosafety clearing house in accordance with Article 11(1) or Article 12(1) of the Cartagena Protocol, as the case may be.

The Commission shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the biosafety clearing house.

2. The Commission shall also process requests for additional information made by any Party in accordance with Article 11(3) of the Cartagena Protocol and shall provide copies of the laws, regulations and guidelines in accordance with Article 11(5) of that Protocol.

Article 45

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission six months after the date of entry into force of this Regulation at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 46

Transitional measures for requests, labelling and notifications

1. Requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be transformed into applications under Chapter II, Section 1 of this Regulation where the initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission, as well as in all cases where an additional assessment report is required in accordance with Article 6(3) or (4) of Regulation (EC) No 258/97. Other requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97, notwithstanding Article 38 of this Regulation.

2. The labelling requirements referred to in this Regulation shall not apply to products, the manufacturing process of which has commenced before the date of application of this Regulation, provided that these products are labelled in accordance with the legislation applicable to them before the date of application of this Regulation.

3. Notifications concerning products including their use as feed submitted under Article 13 of Directive 2001/18/EC before the date of application of this Regulation shall be transformed into applications under Chapter III, Section 1 of this Regulation where the assessment report provided for in Article 14 of Directive 2001/18/EC has not yet been sent to the Commission.

4. Requests submitted for products referred to in Article 15(1)(c) of this Regulation under Article 7 of Directive 82/471/EEC before the date of application of this Regulation shall be transformed into applications under Chapter III, Section 1 of this Regulation.

5. Requests submitted for products referred to in Article 15(1) of this Regulation under Article 4 of Directive 70/524/EEC before the date of application of this Regulation shall be supplemented by applications under Chapter III, Section 1 of this Regulation.

Article 47

Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

1. The presence in food or feed of material which contains, consists of or is produced from GMOs in a proportion no higher than 0,5 % shall not be considered to be in breach of Article 4(2) or Article 16(2), provided that:

(a) this presence is adventitious or technically unavoidable;

(b) the genetically modified material has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before the date of application of this Regulation;

(c) the application for its authorisation has not been rejected in accordance with the relevant Community legislation; and

(d) detection methods are publicly available.

2. In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of such materials.

3. The thresholds referred to in paragraph 1 may be lowered in accordance with the procedure referred to in Article 35(2), in particular for GMOs sold directly to the final consumer.

4. Detailed rules for implementing this Article shall be adopted in accordance with the procedure referred to in Article 35(2).

5. This Article shall remain applicable for a period of three years after the date of application of this Regulation.

Article 48

Review

1. No later than 7 November 2005 and in the light of experience gained, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation and in particular of Article 47, accompanied, where appropriate, by any suitable proposal. The report and any proposal shall be made accessible to the public.

2. Without prejudice to the powers of national authorities, the Commission shall monitor the application of this Regulation and its impact on human and animal health, consumer protection, consumer information and the functioning of the internal market and, if necessary, will bring forward proposals at the earliest possible date.

Article 49

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from six months after the date of publication of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 September 2003.

For the European Parliament
The President
P. COX

For the Council
The President
R. BUTTIGLIONE

ANNEX

DUTIES AND TASKS OF THE COMMUNITY REFERENCE LABORATORY

1. The Community reference laboratory referred to in Article 32 is the Commission's Joint Research Centre.

2. For the tasks outlined in this Annex, the Commission's Joint Research Centre shall be assisted by a consortium of national reference laboratories, which will be referred to as the 'European Network of GMO laboratories'.

3. The Community reference laboratory shall be responsible, in particular, for:

   — reception, preparation, storage, maintenance and distribution to national reference laboratories of the appropriate positive and negative control samples,

   — testing and validation of the method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed,

   — evaluating the data provided by the applicant for authorisation for placing the food or feed on the market, for the purpose of testing and validation of the method for sampling and detection,

   — submitting full evaluation reports to the Authority.

4. The Community reference laboratory shall play a role in dispute settlements between Member States concerning the results of the tasks outlined in this Annex.

ANNEX 3

REGULATION (EC) No 1830/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2003

concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95(1) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [4],

Whereas:

(1) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [5] requires Member States to take measures to ensure traceability and labelling of authorised genetically modified organisms (GMOs) at all stages of their placing on the market.

(2) Differences between national laws, regulations and administrative provisions concerning traceability and labelling of GMOs as products or in products as well as traceability of food and feed produced from GMOs may hinder their free movement, creating conditions of unequal and unfair competition. A harmonised Community framework for traceability and labelling of GMOs should contribute to the effective functioning of the internal market. Directive 2001/18/EC should therefore be amended accordingly.

(3) Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects on human health, animal health or the environment, including ecosystems, are established, and the targeting of monitoring to examine potential effects on, in particular, the environment. Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle.

(4) Traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products, in accordance with the requirements of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [6], so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable control and verification of labelling claims. Requirements for food and feed produced from GMOs should be similar in order to avoid discontinuity of information in cases of change in end use.

(5) The transmission and holding of information that products contain or consist of GMOs, and the unique codes for those GMOs, at each stage of their placing on the market provide the basis for appropriate traceability and labelling for GMOs. The codes may be used to access specific information on GMOs from a register, and to facilitate their identification, detection and monitoring in accordance with Directive 2001/18/EC.

(6) The transmission and holding of information that food and feed have been produced from GMOs also provide the basis for the appropriate traceability of products produced from GMOs.

(7) The Community legislation concerning GMOs as or in feed should also apply to feed intended for animals which are not destined for food production.

(8) Guidance on sampling and detection should be developed in order to facilitate a coordinated approach for control and inspection and provide legal certainty for operators. Account should be taken of registers containing information on genetic modifications in GMOs established by the Commission in accordance with Article 31(2) of Directive 2001/18/EC and Article 29 of Regulation (EC) No 1829/2003.

(9) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation.

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[1] OJ C 304 E, 30.10.2001, p. 327 and OJ C 331 E, 31.12.2002, p. 308.
[2] OJ C 125, 27.5.2002, p. 69.
[3] OJ C 278, 14.11.2002, p. 31.
[4] Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 (OJ C 113 E, 13.5.2003, p. 21), Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal) and Council Decision of 22 July 2003.
[5] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Council Decision 2002/811/EC (OJ L 280, 18.10.2002, p. 27).
[6] See page 1 of this Official Journal.

(10) Certain traces of GMOs in products may be adventitious or technically unavoidable. Such presence of GMOs should therefore not trigger labelling and traceability requirements. It is therefore necessary to fix thresholds for the adventitious or technically unavoidable presence of material consisting, containing or produced from GMOs both when the marketing of such GMOs is authorised in the Community and when their adventitious or technically unavoidable presence is tolerated by virtue of Article 47 of Regulation (EC) No 1829/2003. It is also appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of the above material in a food or feed or in one of its components is higher than the aforesaid labelling thresholds, such presence should be indicated in accordance with the provisions of this Regulation and detailed provisions to be adopted for its implementation.

(11) It is necessary to ensure that consumers are fully and reliably informed about GMOs and the products, foods and feed produced therefrom, so as to allow them to make an informed choice of product.

(12) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1].

(13) Systems for the development and assignment of unique identifiers for GMOs should be established before the measures relating to traceability and labelling can be applied.

(14) The Commission should submit a report to the European Parliament and the Council on the implementation of this Regulation and, more specifically, on the effectiveness of the rules on traceability and labelling.

(15) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union,

HAVE ADOPTED THIS REGULATION:

Article 1

Objectives

This Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.

Article 2

Scope

1. This Regulation shall apply, at all stages of the placing on the market, to:

(a) products consisting of, or containing, GMOs, placed on the market in accordance with Community legislation;

(b) food produced from GMOs, placed on the market in accordance with Community legislation;

(c) feed produced from GMOs, placed on the market in accordance with Community legislation.

2. This Regulation shall not apply to medicinal products for human and veterinary use authorised under Regulation (EEC) No 2309/93 [2].

Article 3

Definitions

For the purpose of this Regulation:

1. 'Genetically modified organism' or 'GMO' means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex IB to Directive 2001/18/EC;

2. 'Produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

3. 'Traceability' means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains;

4. 'Unique identifier' means a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO;

5. 'Operator' means a natural or legal person who places a product on the market or who receives a product that has been placed on the market in the Community, either from a Member State or from a third country, at any stage of the production and distribution chain, but does not include the final consumer;

[1] OJ L 184, 17.7.1999, p. 23.

[2] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal products (OJ L 214, 24.8.1993, p. 1). Regulation as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

6. 'Final consumer' means the ultimate consumer who will not use the product as part of any business operation or activity;

7. 'Food' means food as defined in Article 2 of Regulation (EC) No 178/2002 [1];

8. 'Ingredient' means ingredient as referred to in Article 6(4) of Directive 2000/13/EC [2];

9. 'Feed' means feed as defined in Article 3(4) of Regulation (EC) No 178/2002;

10. 'Placing on the market' means placing on the market as defined in the specific Community legislation under which the relevant product has been authorised; in other cases, it is defined as in Article 2(4) of Directive 2001/18/EC;

11. 'The first stage of the placing on the market of a product' means the initial transaction in the production and distribution chains, where a product is made available to a third party;

12. 'Pre-packaged product' means any single item offered for sale consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

Article 4

Traceability and labelling requirements for products consisting of or containing GMOs

A. TRACEABILITY

1. At the first stage of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

(a) that it contains or consists of GMOs;

(b) the unique identifier(s) assigned to those GMOs in accordance with Article 8.

2. At all subsequent stages of the placing on the market of products referred to in paragraph 1, operators shall ensure that the information received in accordance with paragraph 1 is transmitted in writing to the operators receiving the products.

3. In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, the information referred to in paragraph 1(b) may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

4. Without prejudice to Article 6, operators shall have in place systems and standardised procedures to allow the holding of information specified in paragraphs (1), (2) and (3) and the identification, for a period of five years from each transaction, of the operator by whom and the operator to whom the products referred to in paragraph 1 have been made available.

5. Paragraphs 1 to 4 shall be without prejudice to other specific requirements in Community legislation.

B. LABELLING

6. For products consisting of or containing GMOs, operators shall ensure that:

(a) for pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' appear on a label;

(b) for non-pre-packaged products offered to the final consumer the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' shall appear on, or in connection with, the display of the product.

This paragraph shall be without prejudice to other specific requirements in Community legislation.

C. EXEMPTIONS

7. Paragraphs 1 to 6 shall not apply to traces of GMOs in products in a proportion no higher than the thresholds established in accordance with Article 21(2) or (3) of Directive 2001/18/EC and in other specific Community legislation, provided that these traces of GMOs are adventitious or technically unavoidable.

8. Paragraphs 1 to 6 shall not apply to traces of GMOs in products intended for direct use as food, feed or for processing in a proportion no higher than the thresholds established for those GMOs in accordance with Articles 12, 24 or 47 of Regulation (EC) No 1829/2003, provided that these traces of GMOs are adventitious or technically unavoidable.

[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

[2] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).

Article 5

Traceability requirements for products for food and feed produced from GMOs

1. When placing products produced from GMOs on the market, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:

(a) an indication of each of the food ingredients which is produced from GMOs;

(b) an indication of each of the feed materials or additives which is produced from GMOs;

(c) in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

2. Without prejudice to Article 6, operators shall have in place systems and standardised procedures to allow the holding of the information specified in paragraph 1 and the identification, for a period of five years from each transaction, of the operator by whom and to whom the products referred to in paragraph 1 have been made available.

3. Paragraphs 1 and 2 shall be without prejudice to other specific requirements in Community legislation.

4. Paragraphs 1, 2 and 3 shall not apply to traces of GMOs in products for food and feed produced from GMOs in a proportion no higher than the thresholds established for those GMOs in accordance with Articles 12, 24 or 47 of Regulation (EC) No 1829/2003, provided that these traces of GMOs are adventitious or technically unavoidable.

Article 6

Exemptions

1. In cases where Community legislation provides for specific identification systems, such as lot numbering for prepackaged products, operators shall not be obliged to hold the information specified in Articles 4(1), 4(2), 4(3) and 5(1), provided that this information and the lot number is clearly marked on the package and that information about lot numbers is held for the periods of time referred to in Articles 4(4) and 5(2).

2. Paragraph 1 shall not apply to the first stage of placing on the market of a product or to primary manufacture or repackaging of a product.

Article 7

Amendment of Directive 2001/18/EC

Directive 2001/18/EC is amended as follows:

1. Article 4(6) is deleted;

2. the following paragraph is added to Article 21:

'3. For products intended for direct processing, paragraph 1 shall not apply to traces of authorised GMOs in a proportion no higher than 0,9 % or lower thresholds established under the provisions of Article 30(2), provided that these traces are adventitious or technically unavoidable.'

Article 8

Unique identifiers

In accordance with the procedure referred to in Article 10(2), the Commission shall:

(a) prior to the application of Articles 1 to 7 establish a system for development and assignment of unique identifiers to GMOs;

(b) adapt the system provided for in point (a), as appropriate.

In so doing, account shall be taken of developments in international fora.

Article 9

Inspection and control measures

1. Member States shall ensure that inspections and other control measures including sample checks and testing (qualitative and quantitative), as appropriate, are carried out to ensure compliance with this Regulation. Inspection and control measures may also include inspection and control regarding the holding of a product.

2. Prior to the application of Articles 1 to 7, the Commission, in accordance with the procedure referred to in Article 10(3), shall develop and publish technical guidance on sampling and testing to facilitate a coordinated approach for the implementation of paragraph 1 of this Article. In developing the above technical guidance, the Commission shall take account of the work of national competent authorities, the committee referred to in Article 58(1) of Regulation (EC) No 178/2002 and the Community Reference Laboratory established under Regulation (EC) No 1829/2003.

3. In order to help the Member States meet the requirements set out in paragraphs 1 and 2, the Commission shall ensure that a central register is put in place at Community level, which shall contain all available sequencing information and reference material for GMOs authorised to be put into circulation in the Community. The competent authorities in the Member States shall have access to the register. The register shall also contain, where available, relevant information concerning GMOs which are not authorised in the European Union.

Article 10

Committee

1. The Commission shall be assisted by the committee set up by Article 30 of Directive 2001/18/EC.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. The Committee shall adopt its rules of procedure.

Article 11

Penalties

Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission, not later than 18 April 2004 and shall notify it without delay of any subsequent amendment affecting them.

Article 12

Review clause

No later than 18 October 2005, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation, in particular with regard to Article 4(3) and, where appropriate, bring forward a proposal.

Article 13

Entry into force

1. This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

2. Articles 1 to 7 and Article 9(1) shall apply with effect from the 90th day following the date of publication in the *Official Journal of the European Union* of the measure referred to in Article 8(a).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 September 2003.

For the European Parliament
The President
P. COX

For the Council
The President
R. BUTTIGLIONE

ANNEX 4

I

(Acts whose publication is obligatory)

REGULATION (EC) No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 July 2003 on transboundary movements of genetically modified organisms

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [4],

Whereas:

(1) The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as the Protocol), was signed by the Community and its Member States in 2000 and Council Decision 2002/628/EC [5] to conclude the Protocol, on behalf of the Community, was taken on 25 June 2002.

(2) Article 1 of the Protocol specifies that, in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of genetically modified organisms (GMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movements.

(3) The Protocol requires each Party to take necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [6] invited the Commission to bring forward a legislative proposal for implementing the procedures laid down in the Protocol and, in accordance with the Protocol, requiring Community exporters to ensure that all requirements of the Advance Informed Agreement Procedure, as set out in Articles 7 to 10, 12 and 14 of the Protocol, are fulfilled.

(4) It is important to organise the supervision and control of transboundary movements of GMOs in order to contribute to ensuring the conservation and sustainable use of biological diversity, taking also into account risks to human health, and so as to enable citizens to make a free and informed choice in regard to GMOs.

(5) Since Community legislation does not contain specific requirements for exports of GMOs to third countries, and in order to ensure compliance with the obligations in the Protocol regarding transboundary movements of GMOs, a common legal framework should be established for such exports.

(6) It is necessary to recognise the need to respect the Party or non-Party of import's regulatory biosafety framework, in a manner consistent with the Protocol.

(7) Pharmaceuticals for humans that are addressed by other international agreements, to which the Community or the relevant Member State is party, or organisations, of which the Community or the relevant Member State is a member, should be excluded from the scope of this Regulation.

(8) Exports of GMOs intended for deliberate release into the environment should be notified to the Party or non-Party of import, allowing it to make an informed decision,

[1] OJ C 151 E, 25.6.2002, p. 121.
[2] OJ C 241, 7.10.2002, p. 62.
[3] OJ C 278, 14.11.2002, p. 31.
[4] Opinion of the European Parliament of 24 September 2002 (not yet published in the Official Journal), Council Common Position of 4 March 2003 (OJ C 107 E, 6.5.2003, p. 1), Decision of the European Parliament of 4 June 2003 (not yet published in the Official Journal) and Council Decision of 16 June 2003.
[5] OJ L 201, 31.7.2002, p. 48.
[6] OJ L 106, 17.4.2001, p. 1.

based on a risk assessment carried out in a scientifically sound manner.

(9) The notification should be ensured by the exporter. The exporter should be responsible for the accuracy of the information provided in the notification.

(10) Exporters should await the prior written express consent of the Party or non-Party of import before proceeding with the first transboundary movement of a GMO intended for deliberate release into the environment.

(11) Recognising that some developing countries, and some countries with economies in transition, may lack the capacities which would enable them to take such informed decisions, the Commission and Member States should make sustained efforts to enable them to develop and strengthen human resources and institutional capacities.

(12) According to the Protocol, the Community or any other Party may take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the Protocol, provided that such action is consistent with the objective and the provisions of the Protocol and in accordance with that Party's other obligations under international law.

(13) According to the Protocol, the Community may apply its domestic legislation in respect of the movements of GMOs within its customs territory.

(14) As existing Community legislation, and in particular Directive 2001/18/EC and sectoral legislation providing for a specific risk assessment to be carried out in accordance with the principles set out in that Directive, already contain rules which are in line with the objective of the Protocol, there is no need to adopt supplementary provisions with regard to imports of GMOs into the Community.

(15) It is necessary to ensure the safe transport, handling and packaging of GMOs. As existing Community legislation, in particular Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road [1] and Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail [2], already contain appropriate rules, there is no need to adopt supplementary provisions in this respect.

(16) It is necessary to ensure the identification of GMOs being exported from or imported into the Community. With regard to traceability, labelling and identification of imports into the Community, such GMOs are subject to rules in Community legislation. With regard to exports similar rules should apply.

(17) The Commission and Member States support the process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of GMOs, to be agreed, as provided for in Article 27 of the Protocol, at the first meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.

(18) The Commission and the Member States support the further development and the application of the common formats for accompanying documentation on identification of GMOs, which is undertaken in accordance with Article 18 of the Protocol.

(19) In order to respond efficiently to unintentional transboundary movements of GMOs that are likely to have a significant adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health, a Member State should, as soon as it becomes aware of an event under its jurisdiction resulting in a release that may lead to an unintentional transboundary movement of a GMO that is likely to have such effects, take the appropriate measures to inform the public and inform without delay the Commission, all other Member States, affected or potentially affected States, the Biosafety Clearing-House (BCH) and, where appropriate, relevant international organisations. Also, that Member State should consult without delay affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action.

(20) In order to help develop the BCH, the Community and its Member States should ensure that relevant information is communicated to the BCH, and that monitoring and reporting on the implementation of the Protocol in the Community are performed.

(21) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

(22) The precautionary principle should be taken into account when applying this Regulation.

(23) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union,

[1] OJ L 319, 12.12.1994, p. 7. Directive as last amended by Commission Directive 2003/28/EC (OJ L 90, 8.4.2003, p. 45).
[2] OJ L 235, 17.9.1996, p. 25. Directive as last amended by Commission Directive 2003/29/EC (OJ L 90, 8.4.2003, p. 47).

HAVE ADOPTED THIS REGULATION:

CHAPTER I

OBJECTIVES, SCOPE AND DEFINITIONS

Article 1

Objectives

In accordance with the precautionary principle, and without prejudice to the provisions of Directive 2001/18/EC, the objectives of this Regulation are to establish a common system of notification and information for transboundary movements of genetically modified organisms (GMOs) and to ensure coherent implementation of the provisions of the Protocol on behalf of the Community in order to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 2

Scope

1. This Regulation shall apply to the transboundary movements of all GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health.

2. Pharmaceuticals for humans that are addressed by other relevant international agreements or organisations are excluded from the scope of this Regulation.

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

1. 'organism' means organism as defined in Article 2(1) of Directive 2001/18/EC;

2. 'genetically modified organism', or 'GMO', means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex IB to Directive 2001/18/EC;

3. 'deliberate release' means deliberate release as defined in Article 2(3) of Directive 2001/18/EC;

4. 'placing on the market' means placing on the market as defined in Article 2(4) of Directive 2001/18/EC;

5. 'contained use' means:

   (a) activities defined in Article 2(c) of Directive 90/219/EEC [1];

   (b) activities in which organisms other than micro-organisms are genetically modified or in which such GMOs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures, based on the same principles of containment as in Directive 90/219/EEC, are used appropriately to limit their contact with the general population and the environment;

6. 'food' means food as defined in Article 2 of Regulation (EC) No 178/2002 [2];

7. 'feed' means feed as defined in Article 3(4) of Regulation (EC) No 178/2002;

8. 'notification' means the submission of the information required from the exporter under this Regulation to the competent authority of a Party to the Protocol or to the competent authority of a non-Party;

9. 'the Biosafety Clearing-House' or 'the BCH' means the Biosafety Clearing-House established under Article 20 of the Protocol;

10. 'export' means:

    (a) the permanent or temporary leaving of the customs territory of the Community of GMOs meeting the conditions of Article 23(2) of the Treaty;

    (b) the re-export of GMOs not meeting the conditions referred to in (a) which are placed under a customs procedure other than transit procedure;

11. 'import' means the placing under a customs procedure, other than transit procedure, of GMOs introduced into the customs territory of a Party or non-Party outside the Community from a Party within the Community;

12. 'exporter' means any natural or legal person by whom or on whose behalf a notification is made, that is to say the person who, at the time when the notification is sent, holds the contract with the consignee in the third country and has the power to determine that the GMO is to be sent out of the customs territory of the Community. If no export contract has been concluded or if the holder of the contract does not act on its own behalf, the power to determine that the GMO is to be sent out of the customs territory of the Community shall be decisive;

13. 'importer' means any natural or legal person, under the jurisdiction of the Party or non-Party of Import, who arranges for a GMO to be imported;

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[1] Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (OJ L 117, 8.5.1990, p. 1). Directive as last amended by Decision 2001/204/EC (OJ L 73, 15.3.2001, p. 32).

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

14. 'transboundary movement' means the intentional or unintentional movement of a GMO between one Party or non-Party and another Party or non-Party, excluding intentional movements between Parties within the Community;

15. 'Party' means any country or regional economic integration organisation being a Party to the Protocol;

16. 'non-Party' means any country or regional economic integration organisation not being a Party to the Protocol;

17. 'the Protocol' means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Convention);

18. 'biological diversity' means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems;

19. 'competent authority' means a competent authority designated by a Party to the Protocol, or the relevant equivalent body of a non-Party, which is responsible for performing the administrative functions required by the Protocol, or equivalent functions in the case of a non-Party, and is authorised to act on its behalf with respect to those functions;

20. 'focal point' means the entity designated by a Party to be responsible on its behalf for liaising with the Secretariat;

21. 'Secretariat' means the Secretariat to the Protocol.

CHAPTER II

EXPORTS OF GMOs TO THIRD COUNTRIES

Section 1

GMOs intended for deliberate release into the environment

Article 4

Notification to Parties and non-Parties of import

The exporter shall ensure notification, in writing, to the competent authority of the Party or non-Party of import prior to the first intentional transboundary movement of a GMO intended for deliberate release into the environment and destined for the use specified in accordance with Annex I, point (i). The notification shall contain, as a minimum, the information specified in Annex I. The exporter shall ensure the accuracy of the information contained in the notification.

Article 5

Cases of non-decision

1. A failure by the Party of import to acknowledge receipt of a notification or to communicate its decision shall not imply its consent to an intentional transboundary movement. No first intentional transboundary movement may be made without prior written express consent of the Party or, where appropriate, non-Party of import.

2. In cases where the Party of import does not communicate its decisions in response to a notification within 270 days from the date of receiving the notification, the exporter shall send a written reminder, with a deadline for response of 60 days from receipt of this reminder, to the competent authority of that Party of import, with a copy to the Secretariat, to the Member State of export, and to the Commission. In calculating the time within which a Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account.

3. Without prejudice to paragraph 1, the exporter shall not proceed with the first intentional transboundary movement of a GMO intended for deliberate release unless the procedures determined by the Party of import in accordance with Articles 9 and 10 of the Protocol or, where appropriate, equivalent procedures required by a non-Party of import have been followed.

4. Paragraphs 1, 2 and 3 shall not apply to cases of transboundary movements covered by simplified procedures or bilateral, regional and multilateral agreements or arrangements entered into in accordance with Article 13 and 14 of the Protocol.

5. The Commission and the Member States shall, in consultation with the Secretariat, take appropriate action in accordance with any appropriate procedures and mechanisms to facilitate decision-making or to promote compliance with the provisions of the Protocol by the Parties of import as decided by the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.

Article 6

Informing the Party of export

The exporter shall for a period of a minimum of five years keep a record of the notification referred to in Article 4 and the acknowledgement of receipt and the decision of the Party or, where appropriate, non-Party of import and send a copy of these documents to the competent authority of the Member State from which the GMO is exported and to the Commission.

Without prejudice to Article 16, the Commission shall make these documents available to the public in accordance with the Community rules on access to environmental information.

Article 7

Review of decisions

1. If the exporter considers that a change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based or that additional relevant scientific or technical information has become available, he may ask the Party or, where appropriate, non-Party of import to review a decision it has made concerning notification pursuant to Article 10 of the Protocol.

2. Where a Party or non-Party of import does not respond to such a request within 90 days, the exporter shall send a written reminder to the competent authority of that Party or, where appropriate, non-Party of import, with a copy to the Secretariat, requesting a response within a set period following receipt of the reminder.

Article 8

Exceptions to Section 1 of this Chapter

1. GMOs intended for deliberate release into the environment identified in a decision of the Conference of the Parties to the Convention serving as the Meeting of the Parties to the Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, shall be excluded from the scope of section 1 of this Chapter.

2. Section 1 of this Chapter shall not apply to GMOs intended for direct use as food or feed, or for processing.

3. The obligations referred to in section 1 of this Chapter shall not apply if the Party of import has specified in advance to the BCH, in accordance with Article 13(1)(b) and Article 14(3) of the Protocol, that such imports of GMOs are to be exempted from the Advance Informed Agreement Procedure, as set out in Articles 7 to 10, 12 and 14 of the Protocol, provided that adequate measures are applied to ensure their safe intentional transboundary movement in accordance with the objective of the Protocol.

Section 2

GMOs intended for direct use as food or feed, or for processing

Article 9

Information to the BCH

1. The Commission on behalf of the Community or, where appropriate, the Member State which made the decision shall inform the BCH and other Parties through the BCH of any final decision regarding use, including placing on the market, within the Community or use within a Member State, of a GMO that may be subject to transboundary movements for direct use as food or feed or for processing. This information shall be sent to the BCH within 15 days of the adoption of that decision.

This paragraph shall not apply to decisions regarding the deliberate release in accordance with Part B of Directive 2001/18/EC of a GMO which is not intended for direct use as food or feed or for processing in a third country without a subsequent decision.

2. The information referred to in paragraph 1 and sent to the BCH shall contain as a minimum the information specified in Annex II.

3. The Commission or the Member State referred to in paragraph 1 shall process requests submitted to them by any Party or non-Party for additional information regarding the decisions referred to in paragraph 1.

4. A copy of the information referred to in paragraphs 1, 2 and 3 shall be sent by the Commission or the Member State referred to in paragraph 1, in writing, to the focal point of each Party that informs the Secretariat in advance that it does not have access to the BCH.

Article 10

Parties' and non-Parties' national decisions on import

1. The exporter shall respect any decision on the import of GMOs intended for direct use as food or feed, or for processing, taken by a Party in accordance with Article 11(4) of the Protocol, or by a non-Party of import under its domestic regulatory framework that is consistent with the objective of the Protocol.

2. If a developing country Party or non-Party of import or a Party or non-Party of import with an economy in transition has declared through the BCH that it will take a decision prior to an import of a specific GMO intended for direct use as food or feed, or for processing, in accordance with Article 11(6) of the Protocol, the exporter shall not proceed with the first export of such GMO unless the procedure provided for under that provision has been followed.

3. Failure by the Party or non-Party of import to acknowledge receipt of a notification or to communicate its decision in accordance with paragraph 2 shall not imply its consent or refusal to the import of a GMO intended for direct use as food or feed, or for processing. No GMO that may be subject to transboundary movements for direct use as food or feed or for processing may be exported, unless it is authorised within the Community or the competent authority of a third country has expressly agreed to the import as required under Article 12 of Regulation (EC) No 178/2002.

Section 3

GMOs intended for contained use

Article 11

1. The provisions of Chapter II, section 1 shall not apply to transboundary movements of GMOs intended for contained use where such transboundary movements are undertaken in accordance with the standards of the Party or non-Party of import.

2. Paragraph 1 shall be without prejudice to any right of a Party or non-Party to subject all GMOs to risk assessment prior to decisions on import and to set standards for contained use within their jurisdiction.

Section 4

Common provisions

Article 12

Identification and accompanying documentation

1. Exporters shall ensure that the following information is stated in a document accompanying the GMO and is transmitted to the importer receiving the GMO:

(a) that it contains or consists of GMOs;

(b) the unique identification code(s) assigned to those GMOs if such codes exist.

2. For GMOs intended for direct use as food or feed, or for processing, the information referred to in paragraph 1 shall be supplemented by a declaration by the exporter:

(a) stating that the GMOs are intended for direct use as food or feed, or for processing and indicating clearly that they are not intended for deliberate release into the environment; and

(b) giving details of the contact point for further information.

Paragraph 1(b) shall not apply to products consisting of or containing mixtures of GMOs to be used only and directly as food or feed, or for processing. These products shall be subject to the traceability requirements of Directive 2001/18/EC and, when applicable, future Community legislation covering traceability, labelling and identification of such GMOs.

3. For GMOs intended for contained use, the information referred to in paragraph 1 shall be supplemented by a declaration by the exporter which shall specify:

(a) any requirements for the safe handling, storage, transport and use of these GMOs;

(b) the contact point for further information, including the name and address of the individual or institution to whom or which the GMOs are consigned.

4. For GMOs intended for deliberate release into the environment and any other GMO to which this Regulation applies, the information referred to in paragraph 1 shall be supplemented by a declaration by the exporter which shall set out:

(a) the identity and relevant traits and characteristics of the GMOs;

(b) any requirements for the safe handling, storage, transport and use of these GMOs;

(c) the contact point for further information and, as appropriate, the name and address of the importer and exporter;

(d) a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

5. Paragraph 1 to 4 shall be without prejudice to other specific requirements imposed by Community legislation and to international identification requirements to be developed in accordance with Article 18 of the Protocol.

Article 13

Transit

The exporter shall ensure notification of the transit of GMOs to Parties that have taken the decision to regulate transit of GMOs through their territory and have informed the BCH of this decision.

CHAPTER III

UNINTENTIONAL TRANSBOUNDARY MOVEMENT OF GMOs

Article 14

1. Member States shall take appropriate measures to prevent unintentional transboundary movements of GMOs.

2. As soon as a Member State becomes aware of an occurrence, under its jurisdiction, resulting in a release of GMOs that leads, or may lead, to an unintentional transboundary movement that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, that Member State shall:

(a) take the appropriate measures to inform the public and inform without delay the Commission, all other Member States, affected or potentially affected States, the BCH, and, where appropriate, relevant international organisations;

(b) without delay consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures in order to minimise any significant adverse effects.

3. Any information arising from paragraph 2 shall include the information specified in Annex III.

CHAPTER IV

COMMON PROVISIONS

Article 15

Participation in the international information procedure

1. The Member States shall, without prejudice to the protection of confidential information in accordance with the provisions of the Protocol, inform the BCH and the Commission of:

(a) national legislation and guidelines relevant to the implementation of the Protocol, in accordance with Article 11(5) and Article 20(3)(a) of the Protocol;

(b) national contact points for notification of unintentional transboundary movements, in accordance with Article 17 of the Protocol;

(c) any bilateral, regional and multilateral agreement and arrangements entered into by the Member State regarding intentional transboundary movements of GMOs, in accordance with Article 20(3)(b) of the Protocol;

(d) any information concerning cases of unintentional or illegal transboundary movements pertaining to them, in accordance with Articles 17 and 25 of the Protocol;

(e) any final decision taken by a Member State, on the use of GMOs within that Member State, including decisions:

— on contained use classified in risk class 3 or 4 of GMOs which are likely to be subject to transboundary movements,

— on the deliberate release of GMOs in accordance with part B of Directive 2001/18/EC, or

— on import into the Community of GMOs,

in accordance with Article 11 and Article 20(3)(d) of the Protocol, within 15 days of the adoption of that decision;

(f) any summary of risk assessments or environmental reviews of GMOs generated by the Community's regulatory process and carried out in accordance with Article 15 of the Protocol, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of GMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, in accordance with Article 20(3)(c) of the Protocol;

(g) any review of national decisions regarding an intentional transboundary movement, in accordance with Article 12 of the Protocol;

(h) any decision taken by a Member State on safeguard measures under Article 23 of Directive 2001/18/EC or emergency measures taken by a Member State under Community legislation on genetically modified food and feed.

2. The Commission shall in accordance with the provisions of the Protocol inform, on behalf of the Community, the BCH of:

(a) Community legislation and guidelines relevant for the implementation of the Protocol, in accordance with Article 11(5) and Article 20(3)(a) of the Protocol;

(b) any bilateral, regional and multilateral agreement and arrangements at Community level regarding intentional transboundary movements of GMOs, in accordance with Article 20(3)(b) of the Protocol;

(c) any final decision taken at Community level regarding the use of a GMO within the Community, including decisions on the placing on the market or the importation of a GMO, in accordance with Article 11 and Article 20(3)(d) of the Protocol;

(d) any summary of risk assessments or environmental review of GMOs generated by the Community regulatory process and carried out in accordance with procedures similar to those laid down in Annex II to Directive 2001/18/EC, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of GMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, in accordance with Article 20(3)(c) of the Protocol;

(e) any review of decisions at Community level regarding an intentional transboundary movement, in accordance with Article 12 of the Protocol;

(f) any application of Community legislation instead of the procedures of the Protocol for intentional movements of GMOs within the Community and imports of GMOs into the Community in accordance with Article 14(3) and (4) of the Protocol;

(g) reports submitted pursuant to Article 19 of this Regulation, including those on implementation of the advanced informed agreement procedure, in accordance with Article 20(3)(e) of the Protocol.

Article 16

Confidentiality

1. The Commission and the Member States shall not divulge to third parties any confidential information received or exchanged under this Regulation.

2. The exporter may indicate the information in the notification submitted under Article 4 which should be treated as confidential. Justification shall be given in such cases upon request.

3. In no case may the following information when submitted according to Articles 4, 9 or 12 be kept confidential:

(a) name and address of the exporter and importer,

(b) general description of the GMO or GMOs,

(c) a summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and

(d) any methods and plans for emergency response.

4. If, for whatever reasons, the exporter withdraws the notification, the Member States and the Commission must respect the confidentiality of commercial and industrial information, including research and development information, as well as information on which the Party or non-Party of import and the exporter disagree as to its confidentiality.

Article 17

Competent authorities and focal points

1. The Commission shall designate a Community focal point and shall, where appropriate, identify any Community competent authority.

2. Each Member State shall designate one focal point, as well as one or more competent authorities. A single entity may fulfil the functions of both focal point and competent authority.

3. The Commission, on behalf of the Community, and each Member State respectively shall, no later than the date of entry into force of the Protocol for them, inform the Secretariat of the names and addresses of their focal points and their competent authorities. Where a Member State or the Commission designates more than one competent authority, it shall, when conveying this to the Secretariat, include relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, as a minimum, specify which competent authority is responsible for which type of GMO. The Commission and the Member States shall forthwith inform the Secretariat of any changes in the designation of their focal points or in the name and address or responsibilities of their competent authority or authorities.

Article 18

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measure necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission, by not later than 5 November 2004 and shall notify it without delay of any subsequent amendment affecting them.

Article 19

Monitoring and reporting

1. At regular intervals and at least every three years, unless otherwise determined under Article 33 of the Protocol, Member States shall forward to the Commission a report on the implementation of this Regulation.

2. The Commission shall, at intervals to be determined by the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol, compile a report on the basis of the information provided by the Member States and present it to the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.

Article 20

Entry into force

1. This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

2. This Regulation shall apply from the date of entry into force of the Protocol, in accordance with Article 37(1) of the Protocol, or from the date of entry into force of this Regulation, whichever shall be the later.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 July 2003.

For the European Parliament
The President
P. COX

For the Council
The President
G. TREMONTI

ANNEX I

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLE 4

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the GMO, as well as the domestic classification, if any, of the biosafety level of the GMO in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the GMO.

(i) Intended use of the GMO or products thereof, namely, processed materials that are of GMO origin, containing detectable novel combinations of replicable genetic material obtained through techniques listed in Annex I A, Part 1 of Directive 2001/18/EC.

(j) Quantity or volume of the GMO to be transferred.

(k) A previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the GMO within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the GMO is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the GMO to be transferred.

(o) A declaration that the abovementioned information is factually correct.

ANNEX II

INFORMATION REQUIRED UNDER ARTICLE 9

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the GMO.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the GMO.

(e) Any unique identification of the GMO.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the GMO.

(j) A risk assessment report consistent with Annex II to Directive 2001/18/EC.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

ANNEX III

INFORMATION REQUIRED UNDER ARTICLE 14

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the GMO.

(b) Information on the circumstances and estimated date of the release, and on the use of the GMO in the originating Party.

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures.

(d) Any other relevant information, and

(e) A contact point for further information.

ANNEX 5

COMMISSION REGULATION (EC) No 65/2004

of 14 January 2004

establishing a system for the development and assignment of unique identifiers for genetically modified organisms

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1830/2003, of the European Parliament and of the Council, of 22 September 2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [1], and in particular Article 8 thereof,

Whereas:

(1) Regulation (EC) No 1830/2003 lays down a harmonised framework for the traceability of genetically modified organisms, hereinafter 'GMOs', and of food and feed products produced from GMOs through the transmission and holding of relevant information by operators for such products at each stage of their placing on the market.

(2) Under that Regulation, an operator placing on the market products containing or consisting of GMOs is required to include, as part of that relevant information, the unique identifier assigned to each GMO as a means of indicating its presence and reflecting the specific transformation event covered by the consent or authorisation for placing that GMO on the market.

(3) Unique identifiers should be developed in accordance with a particular format in order to ensure consistency both at Community and international level.

(4) The consent or authorisation granted for the placing on the market of a given GMO under Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2] or other Community legislation should specify the unique identifier for that GMO. Moreover, the person applying for such consent should ensure that the application specifies the appropriate unique identifier.

(5) Where, prior to the entry into force of this Regulation, consents have been granted for the placing on the market of GMOs under Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [3], it is necessary to ensure that a unique identifier is or has been developed, assigned and appropriately recorded for each GMO covered by those consents.

(6) In order to take account of and maintain consistency with developments in international fora, it is appropriate to have regard to the formats for unique identifiers established by the Organisation for Economic Cooperation and Development (OECD), for use in the context of its BioTrack product database and in the context of the Biosafety clearing house established by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

(7) For the purposes of the full application of Regulation (EC) No 1830/2003, it is essential that this Regulation apply as a matter of urgency.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Committee set up under Article 30 of Directive 2001/18/EC,

HAS ADOPTED THIS REGULATION:

CHAPTER I

SCOPE

Article 1

1. This Regulation shall apply to genetically modified organisms, hereinafter 'GMOs', authorised for the placing on the market in accordance with Directive 2001/18/EC or other Community legislation, and applications for placing on the market under such legislation.

2. This Regulation shall not apply to medicinal products for human and veterinary use authorised under Council Regulation (EEC) No 2309/93 [4], or applications for authorisation under that Regulation.

CHAPTER II

APPLICATIONS FOR THE PLACING ON THE MARKET OF GMOs

Article 2

1. Applications for the placing on the market of GMOs shall include a unique identifier for each GMO concerned.

[1] OJ L 268, 18.10.2003, p. 24.
[2] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003.
[3] OJ L 117, 8.5.1990, p. 15. Directive as last amended by Directive 2001/18/EC.
[4] OJ L 214, 24.8.1993, p. 1.

2. Applicants shall, in accordance with the formats set out in the Annex, develop the unique identifier for each GMO concerned, following consultation of the OECD BioTrack product database, and the Biosafety clearing house, to determine whether or not a unique identifier has already been developed for that GMO in accordance with these formats.

Article 3

Where consent or authorisation is granted for the placing on the market of a GMO:

(a) the consent or authorisation shall specify the unique identifier for that GMO;

(b) the Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house;

(c) The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

CHAPTER III

GMOs FOR WHICH CONSENT FOR THEIR PLACING ON THE MARKET HAS BEEN GRANTED PRIOR TO THE ENTRY INTO FORCE OF THIS REGULATION

Article 4

1. Unique identifiers shall be assigned to all GMOs in respect of which, prior to the entry into force of this Regulation, consent has been granted under Directive 90/220/EEC for their placing on the market.

2. Relevant consent holders or where appropriate the competent authority that has taken the final decision on the original application shall consult the OECD BioTrack product database, and the Biosafety clearing house, to determine whether or not a unique identifier has already been developed for that GMO in accordance with the formats set out in the Annex.

Article 5

1. Where, prior to the entry into force of this Regulation, consent has been granted for the placing on the market of a GMO and where a unique identifier has been developed for that GMO in accordance with the formats set out in the Annex, paragraphs 2, 3 and 4 shall apply.

2. Each consent holder, or where appropriate the competent authority that has taken the final decision on the original application, shall within 90 days following the date of entry into force of this Regulation, communicate the following, in writing, to the Commission:

(a) the fact that the unique identifier has already been developed in accordance with the formats set out in the Annex;

(b) the details of the unique identifier.

3. The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

4. The Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house.

Article 6

1. Where, prior to the entry into force of this Regulation, consent has been granted for the placing on the market of a GMO but where a unique identifier has not been developed for that GMO in accordance with the formats set out in the Annex, paragraphs 2, 3, 4 and 5 shall apply.

2. Each consent holder or, where appropriate, the competent authority that has taken the final decision on the original application, shall develop a unique identifier for the GMO concerned in accordance with the formats set out in the Annex.

3. The consent holder shall, within 90 days following the date of entry into force of this Regulation, communicate the details of the unique identifier, in writing, to the competent authority granting consent, which in turn shall immediately transmit these details to the Commission.

4. The unique identifier for each GMO concerned shall be recorded in the relevant registers of the Commission.

5. The Commission, on behalf of the Community, or, where appropriate, the competent authority that has taken the final decision on the original application shall ensure that the unique identifier for that GMO is communicated as soon as possible, in writing, to the Biosafety clearing house.

CHAPTER IV

FINAL PROVISION

Article 7

This Regulation shall enter into force on the date of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 January 2004.

For the Commission
Margot WALLSTRÖM
Member of the Commission

ANNEX

FORMATS FOR UNIQUE IDENTIFIERS

The Annex below defines the format for the unique identifier for plants in Section A and for micro-organisms and animals in Section B.

SECTION A

1. **Overall format**

This Annex provides details as to the format to be used for unique identifiers for GMOs pending or authorised for the placing on the market under Community legislation. The format consists of three components comprising a number of alphanumeric digits and providing reference to the applicant/consent holder, transformation event and a means for verification.

The format comprises nine alphanumeric digits in total. The first component represents the applicant/consent holder and comprises two or three alphanumeric digits. The second component comprises five or six alphanumeric digits and represents the transformation event. The third component provides for verification and is represented by a final numerical digit.

The following provides an example of a unique identifier developed using this format.

C	E	D	-	A	B	8	9	1	-	6

or

C	E	-	A	B	C	8	9	1	-	5

The following sections provide guidance as to how the three individual components of the unique identifier should be developed.

2. **Applicant/consent holder component**

The first two or three alphanumeric digits represent the applicant/consent holder (for example, the first two or three letters of the applicant/consent holder organisation name), followed by a dash, such;

C	E	D	-

or

C	E	-

Applicants may already have assigned alphanumeric digits to indicate their identity and these appear in the applicant's code table within the OECD BioTrack product database. These applicants should continue to use these digits.

Any new applicant that is not identified within the database will not be permitted to use the existing codes listed in the applicant's code table within the database. The new applicant Should inform the national authorities, which should update the OECD BioTrack product database by including a new code (digits) that will be designed to identify the new applicant in the code table.

3. **Transformation event component**

The second set of five or six alphanumerical digits should represent the specific transformation event(s), which is the subject of the application for the placing on the market and/or consent, such as:

A	B	8	9	1	-

or

A	B	C	8	9	1	-

Clearly, an individual transformation event may occur in different organisms, species and varieties and the digits should be representative of the specific event in question. Again, applicants should, prior to formulating unique identifiers, consult the OECD BioTrack product database in terms of the unique identifiers that have been assigned to similar transformation events of the same organism/species in order to provide consistency and to avoid duplication.

Applicants should develop their own internal mechanism to avoid applying the same designation (digits) to a 'transformation event' if used in a different organism. Where similar transformation events are developed by two or more organisations, the 'applicant information' (see section 2) should enable applicants to generate a unique identifier for their own product, while at the same time ensuring its uniqueness from those generated by other applicants.

As regards new GMOs compromising more than one transformation event (often referred to as stacked-gene transformation events), applicants or consent holders should generate a novel unique identifier for such GMOs.

4. **Verification component**

The final digit of the unique identifier is for verification, which shall be separated from the rest of the unique identifier digits by a dash, such as:

- 6

or

- 5

The verification digit is intended to reduce errors by ensuring the integrity of the alphanumeric identifier, entered by the users of the database.

The rule to calculate the verification digit is as follows. The verification digit is made up of a single numerical digit. It is calculated by adding together the numerical values of each of the alphanumerical digits in the unique identifier. The numerical value of each of the digits is from ∅ to 9 for the numerical digits (∅ to 9) and 1 to 26 for the alphabetical digits (A to Z) (see sections 5 and 6). The total sum, if made up of several numerical digits, will be further calculated by adding the remaining digits together using the same rule, in an iterative process, until the final sum is a single numerical digit.For example, the verification digit for the code CED-AB891 is calculated as follows:

step one: 3 + 5 + 4 + 1 + 2 + 8 + 9 + 1 = 33;

step two: 3 + 3 = 6; therefore the verification digit is 6.

Therefore, the final unique identifier then becomes — CED-AB891-6.

5. **Form of digits to be used in the unique identifier**

∅
1
2
3
4
5
6
7
8
9

6. **Form of alphabetic characters to be used, plus numerical equivalents for calculating verification digit.**

A=1
B=2
C=3
D=4
E=5
F=6
G=7
H=8
I=9
J=1ϕ
K=11
L=12
M=13
N=14
O=15
P=16
Q=17
R=18
S=19
T=2ϕ
U=21
V=22
W=23
X=24
Y=25
Z=26

Zero should be reflected by the symbol ϕ to avoid confusion with the letter O.

SECTION B

The provisions of section A of this Annex shall apply to micro-organisms and animals unless another format for a unique identifier is adopted internationally and endorsed at Community level.

ANNEX 6

COMMISSION REGULATION (EC) No 641/2004

of 6 April 2004

on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [1], and in particular Articles 5(7), 8(8), 17(7), 20(8) and 47(4) thereof,

After consulting the European Food Safety Authority in accordance with Articles 5(7) and 17(7) of Regulation (EC) No 1829/2003,

Whereas:

(1) Regulation (EC) No 1829/2003 lays down Community procedures for the authorisation and supervision of genetically modified food and feed and for the labelling of such food and feed.

(2) It is necessary to provide detailed rules concerning applications for authorisations submitted in accordance with Regulation (EC) No 1829/2003.

(3) In addition, Regulation (EC) No 1829/2003 provides that the European Food Safety Authority (the Authority) is to publish detailed guidance to assist the applicant in the preparation and the presentation of the application, concerning notably the information and data to be provided in order to demonstrate that the product complies with the criteria referred to in Articles 4(1) and 16(1) of that Regulation.

(4) In order to ensure a smooth transition to the regime provided by Regulation (EC) No 1829/2003 transitional measures laid down in that Regulation as regards requests and notifications of products falling within the scope of other Community legislation, should be subject to implementing rules.

(5) It is also necessary to provide detailed rules on the preparation and presentation of notifications of existing products submitted to the Commission under Regulation (EC) No 1829/2003 as regards products placed on the market in the Community before 18 April 2004.

(6) Such rules should facilitate the task of operators, in preparing applications for authorisations and in the preparation of notifications of existing products, and the Authority in evaluating such applications and verifying such notifications.

(7) The scope of Regulation (EC) No 1829/2003 includes food which consists of, contains or is produced from genetically modified organisms (GMOs) such as genetically modified plants and micro-organisms. Therefore, in the interests of consistency of Community legislation, the scope of the present Regulation should also cover existing food consisting of, containing or produced from genetically modified plants and micro-organisms.

(8) The scope of Regulation (EC) No 1829/2003 covers feed, including feed additives as defined in Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs [2] consisting of, containing or produced from GMOs such as genetically modified plants and micro-organisms. Therefore, the scope of the present Regulation should also cover existing feed, including feed additives consisting of, containing or produced from genetically modified plants and micro-organisms.

(9) The scope of Regulation (EC) No 1829/2003 does not cover processing aids, including enzymes used as processing aids. Therefore, the scope of the present Regulation similarly should not cover existing processing aids.

[1] OJ L 268, 18.10.2003, p. 1.

[2] OJ L 270, 14.12.1970, p. 1. Directive as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

(10) Regulation (EC) No 1829/2003 provides that detailed rules are to be adopted for implementing the transitional measures for the adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. In the interests of consistency of Community legislation those rules should in particular clarify which genetically modified material is covered by such transitional measures and how the 0,5 % threshold is to be applied.

(11) It is necessary for this Regulation to apply as a matter of urgency as Regulation (EC) No 1829/2003 applies from 18 April 2004.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER I

Applications for authorisation

Article 1

This chapter provides detailed rules concerning applications for authorisation submitted in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, including applications submitted under other Community legislation which are transformed or supplemented in accordance with Article 46 of that Regulation.

SECTION 1

Requirements for applications for authorisation of genetically modified food and feed

Article 2

1. Without prejudice to Article 5(3) and (5) and Article 17(3) and (5) of Regulation (EC) No 1829/2003, and taking into account the guidance of the European Food Safety Authority (the Authority) provided for in Articles 5(8) and 17(8) of that Regulation, applications for authorisation submitted in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 (the applications) shall comply with the requirements of paragraphs 1 to 4 of this Article and with Articles 3 and 4 of this Regulation.

2. In supplying the information required under Article 5(3)(b) and Article 17(3)(b) of Regulation (EC) No 1829/2003, the application shall clearly identify the products covered by it in accordance with Articles 3(1) and 15(1) of that Regulation. Where the application is limited to either food or feed use, it shall contain a verifiable justification explaining why the authorisation should not cover both uses in accordance with Article 27 of Regulation (EC) No 1829/2003.

3. The application shall clearly state which parts of the application are considered to be confidential, together with a verifiable justification in accordance with Article 30 of Regulation (EC) No 1829/2003. Confidential parts shall be submitted in separate documents.

4. The application shall specify, in supplying the information required under Article 5(3)(c) and Article 17(3)(c) of Regulation (EC) No 1829/2003, whether the information included in the application may be notified as such to the biosafety clearing house under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Cartagena Protocol) approved by Council Decision 2002/628/EC ([1]).

If the application may not be notified as such, it shall include the information which complies with Annex II to the Cartagena Protocol and which may be notified to the biosafety clearing house by the Commission as provided in Article 44 of Regulation (EC) No 1829/2003 in a separate and clearly identified document.

5. Paragraph 4 shall not apply to applications concerning only food and feed produced from genetically modified organisms (GMOs) or containing ingredients produced from GMOs.

Article 3

1. The application shall include the following:

(a) the monitoring plan referred to in Article 5(5)(b) and Article 17(5)(b) of Regulation (EC) No 1829/2003, taking into account Council Decision 2002/811/EC ([2]);

(b) in supplying the information required under Article 5(5)(a) and Article 17(5)(a) of Regulation (EC) No 1829/2003, a proposal for labelling complying with the requirements of Annex IV to Directive 2001/18/EC of the European Parliament and of the Council ([3]);

([1]) OJ L 201, 31.7.2002, p. 48.
([2]) OJ L 280, 18.10.2002, p. 27.
([3]) OJ L 106, 17.4.2001, p. 1.

(c) in supplying the information required under Article 5(5)(a) and Article 17(5)(a) of Regulation (EC) No 1829/2003, a proposal for a unique identifier for the GMO in question, developed in accordance with Commission Regulation (EC) No 65/2004 [1];

(d) a proposal for labelling in all official Community languages, where a proposal for specific labelling is needed in accordance with Article 5(3)(f) and Article (g) and 17(3)(f) and (g) of Regulation (EC) No 1829/2003;

(e) a description of a method(s) of detection, sampling and event specific identification of the transformation event, as provided for in Article 5(3)(i) and Article 17(3)(i) of Regulation (EC) No 1829/2003, in accordance with Annex I to this Regulation;

(f) a proposal for post-market monitoring regarding the use of the food for human consumption or the feed for animal consumption, as provided for in Article 5(3)(k) and Article 17(3)(k) of Regulation (EC) No 1829/2003, and according to the characteristics of the products concerned, or a verifiable justification to the effect that a post-market monitoring is not necessary.

2. Points (a), (b) and (c) of paragraph 1 shall not apply to applications concerning only food and feed produced from GMOs or containing ingredients produced from GMOs.

Article 4

1. Samples of the food and feed and their control samples which are to be submitted in accordance with Article 5(3)(j) and Article 17(3)(j) of Regulation (EC) No 1829/2003 shall be in accordance with the requirements set out in Annexes I and II to this Regulation.

The application shall be accompanied by information concerning the place where the reference material developed in accordance with Annex II may be found.

2. The summary to be provided in accordance with Article 5(3)(l) and Article 17(3)(l) of Regulation (EC) No 1829/2003 shall:

(a) be presented in an easily comprehensible and legible form;

(b) not contain parts which are considered to be confidential.

[1] OJ L 10, 16.1.2004, p. 5.

SECTION 2

Transformation of requests and notifications into applications in accordance with Regulation (EC) No 1829/2003

Article 5

1. Where a request submitted under Article 4 of Regulation (EC) No 258/97 of the European Parliament and of the Council [2] is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(1) of that Regulation, the national competent authority of the Member State in which the request was submitted shall, without delay, ask the applicant to submit a complete dossier in accordance with Article 5 of Regulation (EC) No 1829/2003.

2. The national competent authority shall:

(a) acknowledge receipt of the information supplied by the applicant in accordance with paragraph 1 within 14 days of the date of its receipt. The acknowledgement shall state the date of receipt: of the information;

(b) inform the Authority without delay;

(c) make the request and the information supplied by the applicant in accordance with paragraph 1 available to the Authority;

(d) where applicable, make available to the Authority the initial assessment report provided for in Article 6(3) of Regulation (EC) No 258/97, as well as any comments or objections which may have been made by Member States or the Commission under Article 6(4) of that Regulation.

3. The Authority shall:

(a) inform the other Member States and the Commission without delay that the request under Article 4 of Regulation (EC) No 258/97 has been transformed into an application under Regulation (EC) No 1829/2003 and make the application and any supplementary information supplied by the applicant available to them;

(b) make the summary of the dossier referred to in Article 5(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 6(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 5 of Regulation (EC) No 1829/2003.

[2] OJ L 43, 14.2.1997, p. 1.

Article 6

1. Where a notification concerning a product including its use as feed submitted under Article 13 of Directive 2001/18/EC is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(3) of that Regulation, the national competent authority, within the meaning of Directive 2001/18/EC, of the Member State in which the notification was submitted shall ask without delay the notifier to submit a complete dossier in accordance with Article 17 of Regulation (EC) No 1829/2003.

2. The national competent authority shall:

(a) acknowledge receipt of the information supplied by the notifier in accordance with paragraph 1 within 14 days of the date of its receipt; the acknowledgement shall state the date of receipt of the information;

(b) inform the Authority without delay;

(c) make the notification and the information supplied by the notifier in accordance with paragraph 1 available to the Authority;

(d) where applicable, make available to the Authority the assessment report provided for in Article 14(2) of Directive 2001/18/EC.

3. The Authority shall:

(a) inform the other Member States and the Commission without delay that the notification under Article 13 of Directive 2001/18/EC has been transformed into an application under Regulation (EC) No 1829/2003 and shall make the application and any supplementary information supplied by the notifier available to them;

(b) make the summary of the dossier referred to in Article 17(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 18(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

Article 7

1. Where a request submitted under Article 7 of Council Directive 82/471/EEC [1], concerning products produced from GMOs, is transformed into an application under Regulation (EC) No 1829/2003, in accordance with Article 46(4) of that Regulation, the Commission shall ask the applicant without delay to submit a complete dossier in accordance with Article 17 of Regulation (EC) No 1829/2003.

The applicant shall send the complete dossier to the Member States and to the Commission.

2. The Commission shall:

(a) acknowledge receipt of the information supplied by the applicant in accordance with paragraph 1 within 14 days of the date of its receipt; the acknowledgement shall state the date of receipt of the information;

(b) inform the Authority without delay;

(c) make the request and the information supplied by the applicant in accordance with paragraph 1 available to the Authority;

(d) where applicable, make available to the Authority the dossier provided for in Article 7(1) of Directive 82/471/EEC.

3. The Authority shall make:

(a) any supplementary information supplied by the applicant available to the Member States and the Commission;

(b) the summary of the dossier referred to in Article 17(3)(l) of Regulation (EC) No 1829/2003 available to the public.

4. The date of receipt of the application for the purpose of Article 18(1) of Regulation (EC) No 1829/2003 shall be the date of receipt by the Authority of the information referred to in points (c) and (d) of paragraph 2 of this Article.

5. The transformed application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

SECTION 3

Supplementation of requests under Directive 70/524/EEC by an application under Regulation (EC) No 1829/2003

Article 8

1. Where a request submitted under Article 4 of Directive 70/524/EEC, concerning products referred to in Article 15(1) of Regulation (EC) No 1829/2003, is supplemented by an application under Regulation (EC) No 1829/2003, in accordance with Article 46(5) of that Regulation, the Member State acting as rapporteur shall ask the applicant without delay to submit a separate application for authorisation in accordance with Article 17 of Regulation (EC) No 1829/2003.

[1] OJ L 213, 21.7.1982, p. 8.

2. The application shall further be processed as any other application under Article 17 of Regulation (EC) No 1829/2003.

CHAPTER II

Notification of existing products

Article 9

This chapter provides the requirements concerning the preparation and presentation of notifications of existing products submitted to the Commission in accordance with Articles 8 and 20 of Regulation (EC) No 1829/2003 and applies to existing products covered by the scope of that Regulation and placed on the market in the Community prior to 18 April 2004.

SECTION 1

General requirements for notifications of certain products placed on the market before 18 April 2004

Article 10

1. Notifications submitted in accordance with Articles 8(1) and 20(1) of Regulation (EC) No 1829/2003 shall:

(a) clearly identify the products covered by the notification, taking account of Articles 3(1) and 15(1) of Regulation (EC) No 1829/2003;

(b) include relevant information and studies, including, where available, independent and peer-reviewed studies, which demonstrate that the product complies with the requirements provided for in Articles 4(1) or 16(1) of Regulation (EC) No 1829/2003;

(c) clearly indicate which parts of the notification are considered to be confidential, together with a verifiable justification, and those parts shall be submitted in separate documents;

(d) include a method(s) of detection, sampling and identification of the transformation event in accordance with Annex I to this Regulation;

(e) in accordance with Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003 provide:

(i) samples of the food and feed and their control samples in accordance with Annex I to this Regulation;

(ii) information as to the place where the reference material, which shall be developed in accordance with Annex II to this Regulation, may be found.

2. The notifications referred to in paragraph 1 shall be submitted to the Commission before 18 October 2004.

SECTION 2

Additional requirements for notifications of certain products placed on the market before 18 April 2004

Article 11

1. In addition to the requirements of Article 10, notifications of GMOs which have been placed on the market in accordance with part C of Council Directive 90/220/EEC [1] or part C of Directive 2001/18/EC shall include a copy of the relevant consent granted under those directives.

2. The date of publication in the *Official Journal of the European Union* of the Decision to grant consent under Directive 90/220/EEC or Directive 2001/18/EC shall be considered to be the date on which the product was first placed on the market, unless the notifier provides verifiable proof that it was first placed on the market at a later date

Article 12

1. In addition to the requirements of Article 10, notifications of food produced from GMOs which have been placed on the market in accordance with Article 5 of Regulation (EC) No 258/97 shall include a copy of the original notification letter to the Commission.

2. The date of the letter from the Commission forwarding the original notification to the Member States shall be considered to be the date on which the product was first placed on the market, unless the notifier provides verifiable proof that it was first placed on the market at a later date.

Article 13

1. In addition to the requirements of Article 10, notifications of genetically modified food which have been placed on the market in accordance with Articles 6 and 7 of Regulation (EC) No 258/97 shall include a copy of the authorisation of that food.

[1] OJ L 117, 8.5.1990, p. 15.

2. The date the authorisation of the product took effect under Regulation No (EC) 258/97 shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

Article 14

1. In addition to the requirements of Article 10, notifications of feed produced from GMOs which have been placed on the market in accordance with Articles 3 and 4 of Directive 82/471/EEC shall include a copy of the authorisation at Community level or, where applicable, the authorisation granted by a Member State.

2. The date the authorisation of the product took effect in accordance with Directive 82/471/EEC shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

Article 15

1. In addition to the requirements of Article 10, notifications of feed containing, consisting of or produced from GMOs which have been authorised in accordance with Directive 70/524/EEC shall include:

(a) the identification of the feed additive(s) to be covered by the number or the EC number, where applicable, as laid down in Article 9(l) of Directive 70/524/EEC;

(b) a copy of the authorisation.

2. The date the authorisation of the product took effect under Directive 70/524/EEC shall be considered to be the date on which it was first placed on the market, unless the notifier provides verifiable proof that the product was first placed on the market at a later date.

Article 16

In addition to the requirements of Article 10, notifications of feed produced from GMOs which have been lawfully placed on the market in the Community, which are not covered by Articles 11, 14 and 15, and for which the GMO(s) has been notified for authorisation for use as animal feed under part C of Directive 2001/18/EC shall:

(a) contain a reference to the notification under evaluation submitted according to Article 13 of Directive 2001/18/EC;

(b) include a declaration that the product was placed on the market before 18 April 2004.

Article 17

In addition to the requirements of Article 10, notifications of food and feed produced from GMOs which have been lawfully placed on the market in the Community and which are not covered by Articles 11 to 16 shall include a declaration that the product was placed on the market before 18 April 2004.

CHAPTER III

Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

Article 18

1. For the purpose of implementing Article 47 of Regulation (EC) No 1829/2003, the Commission shall, on 18 April 2004, publish a list of the genetically modified material that has benefited from a favourable opinion from the Community Scientific Committee(s) or the Authority before that date and for which an application for authorisation has not been rejected in accordance with the relevant Community legislation.

2. This list shall distinguish between:

(a) material in respect of which the Commission has been informed, by any interested party, that a detection method is publicly available; an indication of where the detection method has been made available shall be included;

(b) material in respect of which the Commission has not yet been informed that a detection method is publicly available.

Any interested party may, at any time, inform the Commission that a detection method for material referred to in point (b) of the first subparagraph is publicly available, with an indication of where the detection method is available.

3. The list referred to in paragraph 1 shall be maintained by the Commission. Amendments to the list may result, in particular, from:

(a) the granting of an authorisation or the rejection of an application for authorisation for material included in the list, in accordance with the relevant Community legislation;

(b) notifications to the Commission, in accordance with Articles 8 or 20 of Regulation (EC) No 1829/2003, that material included in the list has been lawfully placed on the market in the Community before 18 April 2004, or adoption by the Commission of a measure in accordance with Article 8(6) or 20(6) of Regulation (EC) No 1829/2003;

(c) information received by the Commission that a detection method in respect of material included in the list is publicly available.

Information about amendments brought to the list shall be compiled in an Annex to the list.

Article 19

1. The 0,5 % threshold provided for in Article 47(1) of Regulation (EC) No 1829/2003 shall apply to genetically modified material included in part (a) of the list referred to in Article 18(2) of the present Regulation. Where a lower threshold has been established in accordance with Article 47(3) of Regulation (EC) No 1829/2003, it shall be specified in that list.

2. The thresholds provided for in Article 47 of Regulation (EC) No 1829/2003 shall apply to food ingredients considered individually or food consisting of a single ingredient and to feed and each feed of which it is composed.

CHAPTER IV

Final provision

Article 20

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 18 April 2004.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 April 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

METHOD VALIDATION

1. INTRODUCTION

A. For the purpose of implementing Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003, this Annex provides technical provisions on the type of information on detection methods that shall be provided by the applicant and that is needed to verify the preconditions for the fitness of the method. This includes information about the method as such and about the method testing carried out by the applicant. All guidance documents referred to in this Annex or produced by the Community Reference Laboratory (CRL) shall be made available by the CRL.

B. The method acceptance criteria and method performance requirements have been compiled by the European Network of GMO Laboratories (ENGL) in a document entitled 'Definition of minimum performance requirements for analytical methods of GMO testing', which shall be made available by the CRL. 'Method acceptance criteria' are criteria, which should be fulfilled prior to the initiation of any method validation by the CRL. The 'method performance requirements' define the minimum performance criteria that the method should demonstrate upon completion of a validation study carried out by the CRL according to internationally accepted technical provisions and this in order to certify that the method validated is fit for the purpose of enforcement of Regulation (EC) No 1829/2003.

C. The CRL, established under Regulation (EC) No 1829/2003 and assisted by ENGL, will evaluate the provided information for its completeness and fitness for the purpose. Here, the method acceptance criteria recommended by ENGL, which are described under 1(B), will be taken into account.

D. If the information provided about the method is considered adequate and fulfils the method acceptance criteria, the CRL will initiate the validation process for the method.

E. The validation process will be carried out by the CRL according to internationally accepted technical provisions.

F. The CRL, together with ENGL, shall provide further information about the operational procedures of the validation process and shall make the documents available.

G. The CRL, assisted by ENGL, shall evaluate the results obtained in the validation study for the fitness for the purpose. Here, the method performance requirements as described under 1(B) shall be taken into account.

2. INFORMATION ABOUT THE METHOD

A. The method shall refer to all the methodological steps needed to analyse the relevant material in accordance with Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003.

For a particular material this must include the methods for DNA extraction and the subsequent quantification in a polymerase chain reaction (PCR) system. In such a case, the whole process from extraction up to the PCR-technique (or equivalent) constitutes a method. The applicant shall provide information about the whole method.

B. As described in the document referred to under 1(B), ENGL recognises the modularity of a method. According to this principle, the applicant is allowed to refer to existing methods for a certain module(s), if available and appropriate. This could be, for instance, a DNA extraction method from a certain matrix. In such a case, the applicant shall provide experimental data from an in-house validation in which the method module has been successfully applied in the context of the application for authorisation.

C. The applicant shall demonstrate that the method fulfils the following requirements.

1. The method shall be event-specific and thus must only be functional with the GMO or GM based product considered and shall not be functional if applied to other events already authorised; otherwise the method cannot be applied for unequivocal detection/identification/quantification. This shall be demonstrated with a selection of non-target transgenic authorised events and conventional counterparts, in the case of GM plants. This testing shall include closely related events, where relevant, and cases where the limits of the detection are truly tested. The same specificity principle must be applied for products that consist of or contain GMOs other than plants.

2. The method shall be applicable to samples of the food or feed, to the control samples and to the reference material, which is referred to in Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003.

3. The method shall be developed taking the following documents in consideration as appropriate:
   — General requirements and definitions: draft European standard prEN ISO 24276:2002,
   — Nucleic acid extraction prEN ISO 21571:2002,
   — Quantitative nucleic acid based methods: draft European standard prEN ISO 21570:2002,
   — Protein based methods: adopted European standard EN ISO 21572:2002,
   — Qualitative nucleic acid based methods: draft European standard prEN ISO 21569:2002.

D. For the purpose of implementing Articles 5(3)(i) and 17(3)(i) of Regulation (EC) No 1829/2003, the applicant shall provide:

(a) in the case of an application for authorisation covering a GMO, products consisting of or containing a GMO or products produced from a GMO, the event-specific quantitative detection method of the GM material;

(b) in addition, in the case of an application for authorisation covering products produced from a GMO where the genetically modified material is detectable, the event-specific quantitative detection method in the foods or feeds produced from the GMO.

E. The applicant shall provide a complete and detailed description of the method. The following points shall be clearly addressed.

1. Scientific basis: An overview of the principles of how the method works, such as DNA molecular biology based (e.g. for real-time PCR) information must be provided. It is recommended to provide references to relevant scientific publications.

2. Scope of the method: Indication of the matrix (e.g. processed food, raw materials), the type of samples and the percentage range to which the method can be applied.

3. Operational characteristics of the method: The required equipment for the application of the method shall be clearly mentioned, with regard to the analysis *per se* and the sample preparation. Further information of any specific aspects crucial for the application of the method shall also be mentioned here.

4. Protocol: The applicant shall provide a complete optimised protocol of the method. The protocol shall present all the details as required to transfer and apply the method independently in other laboratories. It is recommended to use a protocol template, which can be obtained from the CRL. The protocol shall include details of:
   — analyte to be tested,
   — working conditions, instructions and rules,
   — all the materials needed, including an estimation of their amounts and storage and handling instructions,
   — all the equipment needed, including not only the main equipment such as a PCR system or centrifuge but also small items such as micropipettes and reaction tubes with an indication of their appropriate sizes, etc.,
   — all the steps of the operative protocol, clearly described,
   — instructions for the data recording (e.g. the programme settings or parameters to be included).

5. The prediction model (or alike) needed to interpret results and to make inferences must be described in full details. Instructions for the correct application of the model should be provided.

3. INFORMATION ABOUT THE METHOD TESTING CARRIED OUT BY THE APPLICANT

A. The applicant shall provide all the available and relevant data of the method optimisation and testing carried out. These data and results shall be presented, where possible and appropriate, by using the performance parameters recommended by the ENGL as referred to under 1(B). A summary of the testing carried out and the main results as well as all the data including the outliers shall be provided. The CRL, together with ENGL, shall continue to provide further technical provisions about the appropriate formats for these data.

B. The information provided shall demonstrate the robustness of the method for inter-laboratory transferability. This means that the method should have been tested by at least one laboratory that is independent from the laboratory which has developed the method. This is an important pre-condition for the success of the validation of the method.

C. Information required about the method development and the method optimisation:

1. primer pairs tested (in the case of a PCR-based test): justification shall be given of how and why the proposed primer pair has been selected;

2. stability testing: experimental results from testing the method with different varieties shall be provided;

3. specificity: the applicant shall submit the full sequence of the insert(s), together with the base pairs of the host flanking sequences needed to establish an event-specific detection method. The CRL shall enter these data in a molecular database. By running homology searches, the CRL will thus be in a position to assess the specificity of the proposed method.

D. Testing report. Besides the values obtained for the performance indices, the following information regarding the testing shall be provided, as appropriate:

— participating laboratories, time of the analysis and outline of the experimental design, including the details about the number of runs, samples, replicates etc.,

— description of the laboratory samples (e.g. size, quality, date of sampling), positive and negative controls as well as reference material, plasmids and alike used,

— description of the approaches that have been used to analyse the test results and outliers,

— any particular points observed during the testing,

— references to relevant literature or technical provisions used in the testing.

4. SAMPLES OF THE FOOD AND FEED AND THEIR CONTROL SAMPLES

In view of implementing Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003, the applicant shall, together with the information specified under sections 1, 2 and 3 of this Annex, also provide samples of the food and feed and their control samples of a type and amount to be specified by the CRL for the specific application for authorisation.

ANNEX II

REFERENCE MATERIAL

The reference material as referred to in Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003 shall be produced in accordance with internationally accepted technical provisions such as ISO Guides 30 to 34 (and more particularly ISO Guide 34, specifying the general requirements for the competence of reference material producers). The reference material shall be preferably certified and, if such is the case, certification shall be done in accordance with ISO Guide 35.

For verification and value assignment, a method that has been properly validated (see ISO/IEC 17025:5.4.5) shall be used. Uncertainties have to be estimated according to GUM (ISO Guide to the Expression of Uncertainty in Measurement: GUM). Major characteristics of these internationally accepted technical provisions are given below.

A. Terminology:

reference material (RM): material or substance, one or more of whose property values are sufficiently homogenous and well-established to be used for calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials;

Certified reference material (CRM): reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realisation of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

B. GM RM containers:

— GM RM container (bottles, vials, ampoules, etc.) must be tight and contain not less than the stated amount of material,

— samples must have appropriate homogeneity and stability,

— the commutability of the GM RM has to be assured,

— packaging must be appropriate to the purpose,

— labelling must be of good aspect and quality.

C. Homogeneity testing:

between-bottle homogeneity must be examined;

any possible between-bottle heterogeneity must be accounted for in the overall estimated RM uncertainty. This requirement applies even when no statistically significant between-bottle variation is present. In this case, the method variation or the actual calculated between-bottle variation (whichever is larger) must be included in the overall uncertainty;

D. Stability testing:

stability must be positively demonstrated by appropriate statistical extrapolation for the GM RM shelf-life to be within the stated uncertainty; the uncertainty related to this demonstration is normally part of the estimated RM uncertainty;

assigned values are valid only for a limited time and must be subject to a stability monitoring.

E. Batch characterisation:

the methods used for verification and for certification must:

— be applied under metrologically valid conditions,

— have been properly technically validated before use,

— have precision and accuracy compatible with the target uncertainty;

each set of measurements must:

— be traceable to the stated references, and

— be accompanied by an uncertainty statement whenever possible;

participating laboratories must:

— have the required competence for the execution of the task,

— be able to achieve traceability to the required stated references,

— be able to estimate its measurement uncertainty,

— have in place a sufficient and appropriate quality assurance system.

F. Final storage:

— to avoid a posterior degradation, all samples are best stored under conditions designated for the final storage of the GM RM before measurements are started,

— otherwise, they must be transported from door to door keeping them at all times under such storage conditions for which it has been demonstrated that there is no influence on the assigned values.

G. Establishment of a certificate for CRMs:

— a certificate complemented by a certification report has to be established, containing all information relevant to and needed by the user. The certificate and report must be made available when the GM CRM is distributed,

— certified values must be traceable to stated references and be accompanied by an expanded uncertainty statement valid for the entire shelf-life of the GM CRM.

ANNEX 7

CORRIGENDA

Corrigendum to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

(Official Journal of the European Union L 165 of 30 April 2004)

Regulation (EC) No 882/2004 should read as follows:

REGULATION (EC) No 882/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 29 April 2004

on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95 and 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Having regard to the opinion of the Committee of the Regions [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Feed and food should be safe and wholesome. Community legislation comprises a set of rules to ensure that this objective is attained. These rules extend to the production and the placing on the market of both feed and food.

(2) The basic rules with regard to feed and food law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [4].

(3) In addition to those basic rules, more specific feed and food law covers different areas such as animal nutrition including medicated feedingstuffs, feed and food hygiene, zoonoses, animal by-products, residues and contaminants, control and eradication of animal diseases with a public health impact, feed and food labelling, pesticides, feed and food additives, vitamins, mineral salts, trace elements and other additives, materials in contact with food, quality and compositional requirements, drinking water, ionisation, novel foods and genetically modified organisms (GMOs).

(4) Community feed and food law is based on the principle that feed and food business operators at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that feed and food satisfy the requirements of feed and food law which are relevant to their activities.

(5) Animal health and animal welfare are important factors that contribute to the quality and safety of food, to the prevention of the spreading of animal diseases and to a humane treatment of animals. The rules covering these matters are laid down in several acts. These acts specify the obligations of natural and legal persons with regard to animal health and animal welfare as well as the duties of the competent authorities.

(6) The Member States should enforce feed and food law, animal heath and animal welfare rules and monitor and verify that the relevant requirements thereof are fulfilled by business operators at all stages of production, processing and distribution. Official controls should be organised for that purpose.

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(1) OJ C 234, 30.9.2003, p. 25.

(2) OJ C 23, 27.1.2004, p. 14.

(3) Opinion of the European Parliament of 9 March 2004 (not yet published in the Official Journal) and Council Decision of 26 April 2004.

(4) OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

(7) It is therefore appropriate to establish at Community level a harmonised framework of general rules for the organisation of such controls. It is appropriate to assess in the light of experience whether such a general framework functions properly, in particular in the area of animal health and welfare. It is therefore appropriate for the Commission to present a report together with any necessary proposal.

(8) As a general rule this Community framework should not include official controls with regard to organisms harmful to plants and plant products since these controls are already adequately covered by Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community [1]. Certain aspects of this Regulation should however also apply to the plant health sector and in particular those concerning the establishment of multiannual national control plans and Community inspections within the Member States and in third countries. It is therefore appropriate to amend Directive 2000/29/EC accordingly.

(9) Council Regulations (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs [2], (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [3], and (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs [4] contain specific measures for the verification of compliance with the requirements contained therein. The requirements of this Regulation should be flexible enough so as to take account of the specificity of these areas.

(10) For the verification of compliance with the rules on the common organisation of the markets of agricultural products (arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey) a well established and specific control system is already in place. This Regulation should therefore not apply to these areas, all the more since the objectives of this Regulation differ from the objectives pursued by the control mechanisms for the common organisation of the markets of agricultural products.

(11) The competent authorities for performing official controls should meet a number of operational criteria so as to ensure their impartiality and effectiveness. They should have a sufficient number of suitably qualified and experienced staff and possess adequate facilities and equipment to carry out their duties properly.

(12) The official controls should be carried out using appropriate techniques developed for that purpose, including routine surveillance checks and more intensive controls such as inspections, verifications, audits, sampling and the testing of samples. The correct implementation of those techniques requires appropriate training of the staff performing official controls. Training is also required in order to ensure that the competent authorities take decisions in a uniform way, in particular with regard to the implementation of the hazard analysis and critical control points (HACCP) principles.

(13) The frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or quality assurance programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules. Ad hoc controls should be carried out in case of suspicion of non-compliance. Additionally ad hoc controls could be carried out at any time, even where there is no suspicion of non-compliance.

(14) Official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality.

(15) The competent authorities should ensure that where different control units are involved in carrying out official controls, appropriate coordination procedures are in place and effectively implemented.

[1] OJ L 169, 10.7.2000, p. 1. Directive as last amended by Commission Directive 2004/31/EC (OJ L 85, 23.3.2004, p. 18).

[2] OJ L 198, 22.7.1991, p. 1. Regulation as last amended by Regulation (EC) No 392/2004 (OJ L 65, 3.3.2004, p. 1).

[3] OJ L 208, 24.7.1992, p. 1. Regulation as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

[4] OJ L 208, 24.7.1992, p. 9. Regulation as last amended by Regulation (EC) No 806/2003.

(16) The competent authorities should also ensure that, where the competence to carry out official controls has been delegated from the central level to a regional or local level, there is effective and efficient coordination between the central level and that regional or local level.

(17) Laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated. Such laboratories should in particular have equipment that enables the correct determination of standards such as maximum residue levels fixed by Community law.

(18) The designation of Community and national reference laboratories should contribute to a high quality and uniformity of analytical results. This objective can be achieved by activities such as the application of validated analytical methods, ensuring that reference materials are available, the organisation of comparative testing and the training of staff from laboratories.

(19) The activities of reference laboratories should cover all the areas of feed and food law and animal health, in particular those areas where there is a need for precise analytical and diagnostic results.

(20) For a number of activities related to official controls, the European Committee for Standardisation (CEN) has developed European standards (EN standards) appropriate for the purpose of this Regulation. These EN standards relate in particular to the operation and assessment of testing laboratories and to the operation and accreditation of control bodies. International standards have also been drawn up by the International Organisation for Standardisation (ISO) and the International Union of Pure and Applied Chemistry (IUPAC). These standards might, in certain well defined cases, be appropriate for the purposes of this Regulation, taking into account that performance criteria are laid down in feed and food law in order to ensure flexibility and cost effectiveness.

(21) Provision should be made for delegating competence for performing specific control tasks from the competent authority to a control body, and for the conditions under which such delegation can take place.

(22) Appropriate procedures should be available for the cooperation of the competent authorities in and between the Member States, in particular when official controls reveal that feed and food problems extend to more than one Member State. In order to facilitate such cooperation, Member States should designate one or more liaison bodies with the role of coordinating the transmission and reception of requests for assistance.

(23) In accordance with Article 50 of Regulation (EC) No 178/2002, the Member States shall inform the Commission where information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed is available.

(24) It is important to create uniform procedures for the control of feed and food from third countries introduced into the territory of the Community, taking into account that harmonised import procedures have already been established for food of animal origin by virtue of Council Directive 97/78/EC [1], and for live animals by virtue of Council Directive 91/496/EEC [2].

These existing procedures function properly and should be maintained.

(25) The checks on feed and food from third countries referred to in Directive 97/78/EC are limited to veterinary aspects. It is necessary to supplement these checks with official controls on aspects that are not covered by veterinary checks, such as those on additives, labelling, traceability, irradiation of food and materials in contact with food.

(26) Community legislation also provides for procedures for the control of imported feed by virtue of Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition [3]. That Directive contains principles and procedures that must be applied by the Member States when releasing imported feed for free circulation.

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[1] Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

[2] Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries (OJ L 268, 24.9.1991, p. 56). Directive as last amended by Directive 96/43/EC (OJ L 162, 1.7.1996, p. 1).

[3] OJ L 265, 8.11.1995, p. 17. Directive as last amended by Directive 2001/46/EC of the European Parliament and of the Council (OJ L 234, 1.9.2001, p. 55).

(27) It is appropriate to establish Community rules in order to ensure that feed and food from third countries is submitted to official controls before release for free circulation in the Community. Special attention should be paid to import controls of feed and food for which there may be an increased risk of contamination.

(28) Provision should also be made for the organisation of official controls of feed and food that is introduced into the territory of the Community under customs procedures other than free circulation, and in particular those introduced under the customs procedures referred to in points (b) to (f) of Article 4(16) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [1], as well as their entry into a free zone or free warehouse. This includes the introduction of feed and food from third countries by passengers of international means of transport and through parcels sent by mail.

(29) For the purpose of official controls on feed and food, it is necessary to define the territory of the Community in which the rules apply in order to ensure that feed and food that is introduced into this territory is submitted to the controls laid down by this Regulation. This territory is not necessarily the same as provided for in Article 299 of the Treaty, or as defined in Article 3 of Regulation (EEC) No 2913/92.

(30) In order to ensure a more efficient organisation of the official controls on feed and food from third countries and in order to facilitate commercial flows, it may be necessary to designate specific points of entry for feed and food from third countries into the territory of the Community. Likewise, it may be necessary to require prior notification of the arrival of goods at the territory of the Community. It should be ensured that each designated point of entry has access to the appropriate facilities to operate controls within reasonable time limits.

(31) In establishing rules on the official controls of feed and food from third countries, it should be ensured that the competent authorities and the customs services work together, taking into account the fact that rules to that effect already exist in Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries [2].

(32) Adequate financial resources should be available for organising official controls. Hence, the competent authorities of the Member States should be able to levy the fees or charges to cover the costs incurred through official controls. In the process, the competent authorities of the Member States will be at liberty to establish the fees and charges as flat-rate amounts based on the costs incurred and taking the specific situation of the establishments into account. Where fees are imposed on operators, common principles should apply. It is appropriate therefore to lay down the criteria for setting the level of inspection fees. With regard to fees applicable for import controls, it is appropriate to establish directly the rates for main import items with a view to ensuring their uniform application and to avoiding trade distortions.

(33) Community feed and food law provides for the registration or approval of certain feed and food businesses by the competent authority. This is particularly the case in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [3], Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [3], Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector [4] and the future regulation on feed hygiene.

Procedures should be put in place in order to ensure that registration and approval of feed and food businesses are carried out in an effective and transparent way.

(34) In order to have a global and uniform approach with regard to official controls, Member States should establish and implement multiannual national control plans in accordance with broad guidelines drawn up at Community level. These guidelines should promote coherent national strategies, and identify risk-based priorities and the most effective control procedures. A Community strategy should take a comprehensive, integrated approach to the operation of controls. In view of the non-binding character of certain technical guidelines to be established it is appropriate to establish them by means of a consultative Committee procedure.

(35) The multiannual national control plans should cover feed and food law, and the legislation on animal health and animal welfare.

[1] OJ L 302, 19.10.1992, p. 1. Regulation as last amended by Regulation (EC) No 2700/2000 of the European Parliament and of the Council (OJ L 311, 12.12.2000, p. 17).

[2] OJ L 40, 17.2.1993, p. 1. Regulation as last amended by Regulation (EC) No 806/2003.

[3] OJ L 139, 30.4.2004, p.55.

[4] OJ L 332, 30.12.1995, p. 15. Directive as last amended by Regulation (EC) No 806/2003.

(36) The multiannual national control plans should establish a solid basis for the Commission inspection services to carry out controls in the Member States. The control plans should enable the Commission inspection services to verify whether the official controls in the Member States are organised in accordance with the criteria laid down in this Regulation. Where appropriate and, in particular, where the audit of the Member States against the multiannual national control plans shows weaknesses or failures, detailed inspections and audits should be carried out.

(37) Member States should be required to present an annual report to the Commission with information on the implementation of the multiannual national control plans. This report should provide the results of the official controls and audits carried out during the previous year and, where necessary, an update of the initial control plan in response to these results.

(38) Community controls in the Member States should allow the Commission control services to verify whether feed and food law and the legislation on animal health and animal welfare are implemented in a uniform and correct way throughout the Community.

(39) Community controls in third countries are required in order to verify compliance or equivalence with Community feed and food law as well as with the legislation on animal health and, where appropriate, welfare. Third countries may also be requested to provide information on their control systems. This information, which should be established on the basis of Community guidelines, should form the basis for subsequent Commission controls, which should be carried out within a multidisciplinary framework covering the main sectors exporting to the Community. This evolution should allow a simplification of the current regime, enhance effective control cooperation, and consequently facilitate trade flows.

(40) In order to ensure that imported goods comply with or are equivalent to Community feed and food law, it is necessary to establish procedures that allow the definition of import conditions and certification requirements as appropriate.

(41) Breaches of feed and food law and of animal health and animal welfare rules may constitute a threat to human health, animal health, and animal welfare. Such breaches should therefore be subject to effective, dissuasive and proportionate measures at national level throughout the Community.

(42) Such measures should include administrative action by the competent authorities in the Member States who should have procedures in place for that purpose. The advantage of such procedures is that quick action can be undertaken in order to restore the situation.

(43) Operators should have a right to appeal against the decisions taken by the competent authority as a result of the official controls, and be informed of such a right.

(44) It is appropriate to take account of the special needs of developing countries, and in particular of the least-developed countries, and to introduce measures to that effect. The Commission should be committed to support developing countries with regard to feed and food safety, which is an important element of human health and trade development. Such support should be organised in the context of the Community's development cooperation policy.

(45) The rules contained in this Regulation underpin the integrated and horizontal approach necessary to implement a coherent control policy on feed and food safety, animal health and animal welfare. There should be room however to develop specific control rules where required, for example with regard to the setting of maximum residue levels for certain contaminants at Community level. Likewise, more specific rules existing in the area of feed and food and animal health and animal welfare controls should be kept in place.

These include in particular the following acts: Directive 96/22/EC Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in [1], Directive 96/23/EC [2], Regulation (EC)

[1] stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, (OJ L 125, 23.5.1996, p. 3). Directive as last amended by Directive 2003/74/EC of the European Parliament and of the Council (OJ L 262, 14.10.2003, p. 17).

[2] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23.5.1996, p. 10). Directive as last amended by Regulation (EC) No 806/2003.

No 854/2004 [1], Regulation (EC) No 999/2001 [2], Regulation (EC) No 2160/2003 [3], Directive 86/362/EEC [4], Directive 90/642/EEC [5] and the implementing rules resulting therefrom, Directive 92/1/EEC [6], Directive 92/2/EEC [7], and acts on the control of animal diseases such as foot-and-mouth disease, swine fever etc., as well as requirements on the official controls on the welfare of animals.

(46) This Regulation covers areas that are already covered in certain acts in force at present. It is appropriate therefore to repeal in particular the following acts on feed and food controls and to replace them by the rules of this Regulation: Directive 70/373/EEC [8]; Directive 85/591/EEC [9]; Directive 89/397/EEC [10]; Directive 93/99/EEC [11]; Decision 93/383/EEC [12]; Directive 95/53/EC; Directive 96/43/EC [13]; Decision 98/728/EC [14]; and Decision 1999/313/EC [15].

(47) In the light of this Regulation, Directives 96/23/EC, 97/78/EC and 2000/29/EC should be amended.

(48) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to official controls, cannot be sufficiently achieved by the Member States and can therefore, by reason of its complexity, its trans-border character and, with regard to feed and food imports, its international character, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(49) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [16],

HAVE ADOPTED THIS REGULATION:

TITLE I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at:

(a) preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment;

and

(1) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

(2) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1). Regulation as last amended by Commission Regulation (EC) No 2245/2003 (OJ L 333, 20.12.2003, p. 28).

(3) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).

(4) Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals (OJ L 221, 7.8.1986, p. 37). Directive as last amended by Commission Directive 2004/2/EC (OJ L 14, 21.1.2004, p. 10).

(5) Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (OJ L 350, 14.12.1990, p. 71). Directive as last amended by Commission Directive 2004/2/EC.

(6) Commission Directive 92/1/EEC of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption (OJ L 34, 11.2.1992, p. 28).

(7) Commission Directive 92/2/EEC of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption (OJ L 34, 11.2.1992, p. 30).

(8) Council Directive 70/373/EEC of 20 July 1970 on the introduction of Community methods of sampling and analysis for the official control of feedingstuffs (OJ L 170, 3.8.1970, p. 2). Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

(9) Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption (OJ L 372, 31.12.1985, p. 50). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1)

(10) Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (OJ L 186, 30.6.1989, p. 23)

(11) Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (OJ L 290, 24.11.1993, p. 14). Directive as amended by Regulation (EC) No 1882/2003.

(12) Council Decision 93/383/EEC of 14 June 1993 of reference laboratories for the monitoring of marine biotoxins (OJ L 166, 8.7.1993, p. 31). Decision as amended by Decision 1999/312/EC (OJ L 120, 8.5.1999, p. 37).

(13) Council Directive 96/43/EC of 26 June 1996 amending and consolidating Directive 85/73/EEC in order to ensure financing of veterinary inspections and controls on live animals and certain animal products (OJ L 162, 1.7.1996, p. 1).

(14) Council Decision 98/728/EC of 14 December 1998 concerning a Community system for fees in the animal feed sector (OJ L 346, 22.12.1998, p. 51).

(15) Council Decision 1999/313/EC of 29 April 1999 on reference laboratories for monitoring bacteriological and viral contamination of bivalve molluscs (OJ L 120, 8.5.1999, p. 40).

(16) OJ L 184, 17.7.1999, p. 23.

(b) guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information.

2. This Regulation shall not apply to official controls for the verification of compliance with the rules on common market organisations of agricultural products.

3. This Regulation shall be without prejudice to specific Community provisions concerning official controls.

4. The performance of official controls pursuant to this Regulation shall be without prejudice to feed and food business operators' primary legal responsibility for ensuring feed and food safety, as laid down in Regulation (EC) No 178/2002, and any civil or criminal liability arising from the breach of their obligations.

Article 2

Definitions

For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 shall apply.

The following definitions shall also apply:

1. 'official control' means any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules;

2. 'verification' means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled;

3. 'feed law' means the laws, regulations and administrative provisions governing feed in general and feed safety in particular, whether at Community or national level; it covers all stages of production, processing and distribution of feed and the use of feed;

4. 'competent authority' means the central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country;

5. 'control body' means an independent third party to which the competent authority has delegated certain control tasks;

6. 'audit' means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;

7. 'inspection' means the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and animal welfare rules;

8. 'monitoring' means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed or food law, animal health and animal welfare rules;

9. 'surveillance' means a careful observation of one or more feed or food businesses, feed or food business operators or their activities;

10. 'non-compliance' means non-compliance with feed or food law, and with the rules for the protection of animal health and welfare;

11. 'sampling for analysis' means taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or food or to the health of animals, in order to verify through analysis compliance with feed or food law or animal health rules;

12. 'official certification' means the procedure by which the competent authority or control bodies, authorised to act in such a capacity, provide written, electronic or equivalent assurance concerning compliance;

13. 'official detention' means the procedure by which the competent authority ensures that feed or food is not moved or tampered with pending a decision on its destination; it includes storage by feed and food business operators in accordance with instructions from the competent authority;

14. 'equivalence' means the capability of different systems or measures to meet the same objectives; and 'equivalent' means different systems or measures capable of meeting the same objectives;

15. 'import' means the release for free circulation of feed or food or the intention to release feed or food for free circulation within the meaning of Article 79 of Regulation (EEC) No 2913/92 in one of the territories referred to in Annex I;

16. 'introduction' means import as defined in point 15 above, and the placing of goods under the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92, as well as their entry into a free zone or free warehouse;

17. 'documentary check' means the examination of commercial documents and, where appropriate, of documents required under feed or food law that are accompanying the consignment;

18. 'identity check' means a visual inspection to ensure that certificates or other documents accompanying the consignment tally with the labelling and the content of the consignment;

19. 'physical check' means a check on the feed or food itself which may include checks on the means of transport, on the packaging, labelling and temperature, the sampling for analysis and laboratory testing and any other check necessary to verify compliance with feed or food law;

20. 'control plan' means a description established by the competent authority containing general information on the structure and organisation of its official control systems.

TITLE II

OFFICIAL CONTROLS BY MEMBER STATES

CHAPTER I

GENERAL OBLIGATIONS

Article 3

General obligations with regard to the organisation of official controls

1. Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Regulation taking account of:

(a) identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare;

(b) feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules;

(c) the reliability of any own checks that have already been carried out;

and

(d) any information that might indicate non-compliance.

2. Official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an ad hoc basis.

3. Official controls shall be carried out at any of the stages of production, processing and distribution of feed or food and of animals and animal products. They shall include controls on feed and food businesses, on the use of feed and food, on the storage of feed and food, on any process, material, substance, activity or operation including transport applied to feed or food and on live animals, required to achieve the objectives of this Regulation.

4. Official controls shall be applied, with the same care, to exports outside the Community, to the placing on the market within the Community and to introductions from third countries into the territories referred to in Annex I.

5. Member States shall take all necessary measures to ensure that products intended for dispatch to another Member State are controlled with the same care as those intended to be placed on the market in their own territory.

6. The competent authority of the Member State of destination may check compliance of feed and food with feed and food law by means of non-discriminatory checks. To the extent strictly necessary for the organisation of the official controls, Member States may ask operators who have goods delivered to them from another Member State to report the arrival of such goods.

7. If, during a check carried out at the place of destination or during storage or transport, a Member State establishes non-compliance, it shall take the appropriate measures, which may include re-dispatch to the Member State of origin.

CHAPTER II

COMPETENT AUTHORITIES

Article 4

Designation of competent authorities and operational criteria

1. Member States shall designate the competent authorities responsible for the purposes and official controls set out in this Regulation.

2. The competent authorities shall ensure:

(a) the effectiveness and appropriateness of official controls on live animals, feed and food at all stages of production, processing and distribution, and on the use of feed;

(b) that staff carrying out official controls are free from any conflict of interest;

(c) that they have, or have access to, an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively;

(d) that they have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively;

(e) that they have the legal powers to carry out official controls and to take the measures provided for in this Regulation;

(f) that they have contingency plans in place, and are prepared to operate such plans in the event of an emergency;

(g) that the feed and food business operators are obliged to undergo any inspection carried out in accordance with this Regulation and to assist staff of the competent authority in the accomplishment of their tasks.

3. When a Member State confers the competence to carry out official controls on an authority or authorities other than a central competent authority, in particular those at regional or local level, efficient and effective coordination shall be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection.

4. Competent authorities shall ensure the impartiality, quality and consistency of official controls at all levels. The criteria listed in paragraph 2 must be fully respected by every authority on which the competence to carry out official controls is conferred.

5. When, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

6. Competent authorities shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Regulation. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.

7. Detailed rules for the implementation of this Article may be adopted in accordance with the procedure referred to in Article 62(3).

Article 5

Delegation of specific tasks related to official controls

1. The competent authority may delegate specific tasks related to official controls to one or more control bodies in accordance with paragraphs 2 to 4.

A list of tasks that may or may not be delegated may be established in accordance with the procedure referred to in Article 62(3).

However, the activities referred to in Article 54 shall not be the subject of such a delegation.

2. The competent authority may delegate specific tasks to a particular control body only if:

(a) there is an accurate description of the tasks that the control body may carry out and of the conditions under which it may carry them out;

(b) there is proof that the control body:

(i) has the expertise, equipment and infrastructure required to carry out the tasks delegated to it;

(ii) has a sufficient number of suitably qualified and experienced staff;

and

(iii) is impartial and free from any conflict of interest as regards the exercise of the tasks delegated to it;

(c) the control body works and is accredited in accordance with European Standard EN 45004 'General criteria for the operation of various types of bodies performing inspection' and/or another standard if more relevant to the delegated tasks in question;

(d) laboratories operate in accordance with the standards referred to in Article 12(2);

(e) the control body communicates the results of the controls carried out to the competent authority on a regular basis and whenever the competent authority so requests. If the results of the controls indicate non-compliance or point to the likelihood of non-compliance, the control body shall immediately inform the competent authority;

(f) there is efficient and effective coordination between the delegating competent authority and the control body.

3. Competent authorities delegating specific tasks to control bodies shall organise audits or inspections of control bodies as necessary. If, as a result of an audit or an inspection, it appears that such bodies are failing to carry out properly the tasks delegated to them, the delegating competent authority may withdraw the delegation. It shall withdraw it without delay if the control body fails to take appropriate and timely remedial action.

4. Any Member State wishing to delegate a specific control task to a control body shall notify the Commission. This notification shall provide a detailed description of:

(a) the competent authority that would delegate the task;

(b) the task that it would delegate;

and

(c) the control body to which it would delegate the task.

Article 6

Staff performing official controls

The competent authority shall ensure that all of its staff performing official controls:

(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner. This training shall cover as appropriate the areas referred to in Annex II, Chapter I;

(b) keep up to date in their area of competence and receive regular additional training as necessary;

and

(c) have aptitude for multidisciplinary cooperation.

Article 7

Transparency and confidentiality

1. The competent authorities shall ensure that they carry out their activities with a high level of transparency. For that purpose, relevant information held by them shall be made available to the public as soon as possible.

In general, the public shall have access to:

(a) information on the control activities of the competent authorities and their effectiveness;

and

(b) information pursuant to Article 10 of Regulation (EC) No 178/2002.

2. The competent authority shall take steps to ensure that members of their staff are required not to disclose information acquired when undertaking their official control duties which by its nature is covered by professional secrecy in duly justified cases. Protection of professional secrecy shall not prevent the dissemination by the competent authorities of information referred to in paragraph 1(b). The rules of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1] remain unaffected.

3. Information covered by professional secrecy includes in particular:

— the confidentiality of preliminary investigation proceedings or of current legal proceedings,

— personal data,

— the documents covered by an exception in Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [2],

— information protected by national and Community legislation concerning in particular professional secrecy, the confidentiality of deliberations, international relations and national defence.

Article 8

Control and verification procedures

1. Competent authorities shall carry out official controls in accordance with documented procedures. These procedures shall contain information and instructions for staff performing official controls including, *inter alia*, the areas referred to in Annex II, Chapter II.

[1] OJ L 281, 23.11.1995, p. 31. Directive as amended by Regulation (EC) No 1882/2003.

[2] OJ L 145, 31.5.2001, p. 43.

2. Member States shall ensure that they have legal procedures in place in order to ensure that staff of the competent authorities have access to premises of and documentation kept by feed and food business operators so as to be able to accomplish their tasks properly.

3. Competent authorities shall have procedures in place:

(a) to verify the effectiveness of official controls that they carry out;

and

(b) to ensure that corrective action is taken when needed and that the documentation referred to in paragraph 1 is updated as appropriate.

4. The Commission may establish guidelines for official controls in accordance with the procedure referred to in Article 62(2).

The guidelines may, in particular, contain recommendations concerning official controls on:

(a) the implementation of HACCP principles;

(b) management systems that feed or food business operators operate with a view to meeting the requirements of feed or food law;

(c) the microbiological, physical and chemical safety of feed and food.

Article 9

Reports

1. The competent authority shall draw up reports on the official controls that it has carried out.

2. These reports shall include a description of the purpose of the official controls, the control methods applied, the results of the official controls and, where appropriate, action that the business operator concerned is to take.

3. The competent authority shall provide the business operator concerned with a copy of the report referred to in paragraph 2, at least in case of non-compliance.

Article 10

Control activities, methods and techniques

1. Tasks related to official controls shall, in general, be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.

2. Official controls on feed and food shall include, *inter alia,* the following activities:

(a) examination of any control systems that feed and food business operators have put in place and the results obtained;

(b) inspection of:

(i) primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food;

(ii) raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food;

(iii) semi-finished products;

(iv) materials and articles intended to come into contact with food;

(v) cleaning and maintenance products and processes, and pesticides;

(vi) labelling, presentation and advertising;

(c) checks on the hygiene conditions in feed and food businesses;

(d) assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and HACCP, taking into account the use of guides established in accordance with Community legislation;

(e) examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;

(f) interviews with feed and food business operators and with their staff;

(g) the reading of values recorded by feed or food business measuring instruments;

(h) controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators;

(i) any other activity required to ensure that the objectives of this Regulation are met.

CHAPTER III

SAMPLING AND ANALYSIS

Article 11

Methods of sampling and analysis

1. Sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or,

(a) if no such rules exist, with internationally recognised rules or protocols, for example those that the European Committee for Standardisation (CEN) has accepted or those agreed in national legislation;

or,

(b) in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols.

2. Where paragraph 1 does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol.

3. Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Annex III.

4. The following implementing measures may be taken in accordance with the procedure referred to in Article 62(3):

(a) methods of sampling and analysis, including the confirmatory or reference methods to be used in the event of a dispute;

(b) performance criteria, analysis parameters, measurement uncertainty and procedures for the validation of the methods referred to in (a);

and

(c) rules on the interpretation of results.

5. The competent authorities shall establish adequate procedures in order to guarantee the right of feed and food business operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion, without prejudice to the obligation of competent authorities to take prompt action in case of emergency.

6. In particular, they shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate.

7. Samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.

Article 12

Official laboratories

1. The competent authority shall designate laboratories that may carry out the analysis of samples taken during official controls.

2. However, competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European standards:

(a) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';

(b) EN 45002 on 'General criteria for the assessment of testing laboratories';

(c) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition',

taking into account criteria for different testing methods laid down in Community feed and food law.

3. The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.

4. The competent authority may cancel the designation referred to in paragraph 1 when the conditions referred to in paragraph 2 are no longer fulfilled.

CHAPTER IV

CRISIS MANAGEMENT

Article 13

Contingency plans for feed and food

1. For the implementation of the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002, Member States shall draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment.

2. These contingency plans shall specify:

(a) the administrative authorities to be engaged;

(b) their powers and responsibilities;

and

(c) channels and procedures for sharing information between the relevant parties.

3. Member States shall review these contingency plans as appropriate, particularly in the light of changes in the organisation of the competent authority and of experience, including experience gained from simulation exercises.

4. Where necessary, implementing measures may be adopted in accordance with the procedure referred to in Article 62(3). Such measures shall establish harmonised rules for contingency plans to the extent necessary to ensure that such plans are compatible with the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002. They shall also indicate the role of stakeholders in the establishment and operation of contingency plans.

CHAPTER V

OFFICIAL CONTROLS ON THE INTRODUCTION OF FEED AND FOOD FROM THIRD COUNTRIES

Article 14

Official controls on feed and food of animal origin

1. This Regulation shall not affect the requirements for veterinary checks on feed and food of animal origin provided for in Directive 97/78/EC. However, the competent authority designated in accordance with Directive 97/78/EC shall, in addition, carry out official controls to verify compliance with aspects of feed or food law that that Directive does not cover, as appropriate, including those aspects referred to in Title VI, Chapter II of this Regulation.

2. The general rules of Articles 18 to 25 of this Regulation shall also apply to official controls on all feed and food, including feed and food of animal origin.

3. Satisfactory results of checks on goods that are:

(a) placed under one of the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92;

or

(b) to be handled in free zones or free warehouses, as defined in Article 4(15)(b) of Regulation (EEC) No 2913/92,

shall neither affect the duty of feed and food business operators to ensure that feed and food comply with feed and food law from the moment of release for free circulation nor prevent further official controls on the feed or food concerned from being carried out.

Article 15

Official controls on feed and food of non-animal origin

1. The competent authority shall carry out regular official controls on feed and food of non-animal origin not included in the scope of Directive 97/78/EC, imported into the territories referred to in Annex I. It shall organise these controls on the basis of the multi-annual national control plan drawn up in accordance with Articles 41 to 43 and in the light of potential risks. The controls shall cover all aspects of feed and food law.

2. These controls shall be carried out at an appropriate place, including the point of entry of the goods into one of the territories referred to in Annex I, the point of release for free circulation, warehouses, the premises of the importing feed and food business operator, or other points of the feed and food chain.

3. These controls may also be carried out on goods that are:

(a) placed under one of the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92;

or

(b) to enter free zones or free warehouses, as defined in Article 4(15)(b) of Regulation (EEC) No 2913/92.

4. Satisfactory results of checks referred to in paragraph 3 shall neither affect the duty of feed and food business operators to ensure that feed and food comply with feed and food law from the moment of release for free circulation nor prevent further official controls on the feed or food concerned from being carried out.

5. A list of feed and food of non-animal origin that is, on the basis of known or emerging risk, to be subject to an increased level of official controls at the point of entry into territories referred to in Annex I shall be drawn up and updated, in accordance with the procedure referred to in Article 62(3). The frequency and nature of these controls shall be laid down in accordance with the same procedure. At the same time, the fees related to such controls may be established in accordance with the same procedure.

Article 16

Types of checks on feed and food of non-animal origin

1. The official controls referred to in Article 15(1) shall include at least a systematic documentary check, a random identity check and, as appropriate, a physical check.

2. Physical checks shall be carried out at a frequency depending on:

(a) the risks associated with different types of feed and food;

(b) the history of compliance with the requirements for the product concerned of the third country and establishment of origin and of the feed or food business operators importing and exporting the product;

(c) the controls that the feed or food business operator importing the product has carried out;

(d) the guarantees that the competent authority of the third country of origin has given.

3. The Member States shall ensure that physical checks are carried out under appropriate conditions and at a place with access to appropriate control facilities allowing investigations to be conducted properly, a number of samples adapted to the risk management to be taken, and the feed and food to be handled hygienically. Samples must be handled in such a way as to guarantee both their legal and analytical validity. Member States shall ensure that the equipment and methodology are adequate for measuring the limit values laid down under Community or national legislation.

Article 17

Points of entry and prior notification

1. Member States shall, for the organisation of the official controls referred to in Article 15(5):

— designate particular points of entry in their territory which have access to the appropriate control facilities for different types of feed and food;

and

— require feed and food business operators responsible for consignments to give prior notification of their arrival and nature.

Member States may apply the same rules for other feed of non-animal origin.

2. Member States shall inform the Commission and other Member States of any measures that they take in accordance with paragraph 1.

They shall design those measures in such a way as to avoid unnecessary disruption of trade.

Article 18

Action in case of suspicion

In case of suspicion of non-compliance or if there is doubt as to the identity or the actual destination of the consignment, or as to the correspondence between the consignment and the certified guarantees, the competent authority shall carry out official controls in order to confirm or to eliminate the suspicion or doubt. The competent authority shall place the consignment concerned under official detention until it obtains the results of such official controls.

Article 19

Action following official controls on feed and food from third countries

1. The competent authority shall place under official detention feed or food from third countries that does not comply with feed or food law and, having heard the feed or food business operators responsible for the consignment, it shall take the following measures in respect of such feed or food:

(a) order that such feed or food be destroyed, subjected to a special treatment in accordance with Article 20 or re-dispatched outside the Community in accordance with Article 21; other appropriate measures such as the use of feed or food for purposes other than those for which they were originally intended may also be taken;

(b) if the feed or food has already been placed on the market, monitor or, if necessary, order its recall or withdrawal before taking one of the measures referred to above;

(c) verify that feed and food does not give rise to any adverse effects on human or animal health, either directly or through the environment, during or pending the implementation of any of the measures referred to in subparagraphs (a) and (b).

2. If, however:

(a) the official controls provided for in Articles 14 and 15 indicate that a consignment is injurious to human or animal health or unsafe, the competent authority shall place the consignment in question under official detention pending its destruction or any other appropriate measure necessary to protect human and animal health;

(b) feed or food of non-animal origin for which an increased level of controls has been laid down in accordance with

Article 15(5) is not presented for official controls, or is not presented in accordance with any specific requirements established in accordance with Article 17, the competent authority shall order that it be recalled and placed under official detention without delay and that it be then either destroyed or re-dispatched in accordance with Article 21.

3. When it does not permit the introduction of feed or food, the competent authority shall notify the Commission and other Member States of its findings and of the identification of the products concerned in accordance with the procedure provided for in Article 50(3) of Regulation (EC) No 178/2002 and shall notify its decisions to the customs services, together with information as regards the final destination of the consignment.

4. Decisions on consignments shall be subject to the right of appeal referred to in Article 54(3).

Article 20

Special treatment

1. The special treatment referred to in Article 19 may include:

(a) treatment or processing to bring the feed or food into line with the requirements of Community law, or with the requirements of a third country of re-dispatch, including decontamination, where appropriate, but excluding dilution;

(b) processing in any other suitable manner for purposes other than animal or human consumption.

2. The competent authority shall ensure that special treatment takes place in establishments under its control, or under the control of another Member State, and in accordance with conditions laid down in accordance with the procedure referred to in Article 62(3) or, in the absence of such conditions, with national rules.

Article 21

Re-dispatch of consignments

1. The competent authority shall allow re-dispatch of consignments only if:

(a) the destination has been agreed with the feed or food business operator responsible for the consignment; and

(b) the feed and food business operator has first informed the competent authority of the third country of origin or third country of destination, if different, of the reasons and circumstances preventing the placing on the market of the feed or food concerned within the Community;

and

(c) when the third country of destination is not the third country of origin, the competent authority of the third country of destination has notified the competent authority of its preparedness to accept the consignment.

2. Without prejudice to the national rules applicable with respect to the time limits for applying for a supplementary expert opinion, and where the results of official controls do not preclude it, re-dispatch shall, as a general rule, take place no more than 60 days after the day on which the competent authority decided on the destination of the consignment, unless legal action has been undertaken. If, after the expiry of the 60-day period, re-dispatch does not take place, the consignment shall be destroyed, unless a delay is justified.

3. Pending re-dispatch of consignments or confirmation of the reasons for rejection, the competent authority shall place consignments under official detention.

4. The competent authority shall notify the Commission and other Member States in accordance with the procedure provided for in Article 50(3) of Regulation (EC) No 178/2002 and shall notify its decisions to the customs services. Competent authorities shall cooperate in accordance with Title IV to take any further measures necessary to ensure that it is not possible to reintroduce the rejected consignments into the Community.

Article 22

Costs

The feed or food business operator responsible for the consignment or its representative shall be liable for the costs incurred by competent authorities for the activities referred to in Articles 18, 19, 20 and 21.

Article 23

Approval of pre-export checks by third countries

1. Specific pre-export checks that a third country carries out on feed and food immediately prior to export to the Community with a view to verifying that the exported products satisfy Community requirements may be approved in accordance with the procedure referred to in Article 62(3). The approval may apply only to feed and food originating in the third country concerned and may be granted for one or more products.

2. Where such approval has been granted, the frequency of import controls for feed or food may be reduced as a consequence. However, Member States shall carry out official controls on feed and food imported in accordance with the approval referred to in paragraph 1 so as to ensure that the pre-export checks carried out in the third country remain effective.

3. The approval referred to in paragraph 1 may only be granted to a third country if:

(a) a Community audit has shown that feed or food exported to the Community meets Community requirements, or equivalent requirements;

(b) the controls carried out in the third country prior to dispatch are considered sufficiently effective and efficient as to replace or reduce the documentary, identity and physical checks laid down in Community law.

4. The approval referred to in paragraph 1 shall specify the competent authority of the third country under the responsibility of which the pre-export checks are performed and, if appropriate, any control body to which that competent authority may delegate certain tasks. Such delegation may be approved only if it meets the criteria of Article 5 or equivalent conditions.

5. The competent authority and any control body specified in the approval shall be responsible for contacts with the Community.

6. The competent authority or control body of the third country shall ensure the official certification of each consignment checked prior to its entry into one of the territories referred to in Annex I. The approval referred to in paragraph 1 shall specify a model for such certificates.

7. Without prejudice to Article 50(3) of Regulation (EC) No 178/2002, when official controls on imports subject to the procedure referred to in paragraph 2 reveal significant non-compliance, Member States shall immediately notify the Commission and other Member States and the operators concerned in accordance with the procedure provided for in Title IV of this Regulation; Member States shall increase the number of consignments checked and, where necessary to allow a proper analytical examination of the situation, keep an appropriate number of samples under appropriate storage conditions.

8. If it is found that, in a significant number of consignments, the goods do not correspond to the information in the certificates that the competent authority or control body of the third country has issued, the reduced frequency referred to in paragraph 2 shall no longer apply.

Article 24

Competent authorities and customs services

1. For the organisation of the official controls referred to in this Chapter, the competent authorities and the customs services shall cooperate closely.

2. With regard to consignments of feed and food of animal origin and of feed and food referred to in Article 15(5), customs services shall not allow their entry or handling in free zones or free warehouses without the agreement of the competent authority.

3. Where samples are taken, the competent authority shall inform the customs services and the operators concerned and indicate whether or not the goods can be released before the results of the analysis of the samples are available, provided the traceability of the consignment is ensured.

4. In the case of release for free circulation, competent authorities and customs services shall work together in accordance with the requirements laid down in Articles 2 to 6 of Regulation (EEC) No 339/93.

Article 25

Implementing measures

1. Measures necessary to ensure the uniform implementation of official controls on the introduction of feed and food shall be laid down in accordance with the procedure referred to in Article 62(3).

2. In particular, detailed rules may be laid down for:

(a) feed and food imported or placed under one of the customs procedures referred to in Article 4(16)(b) to (f) of Regulation (EEC) No 2913/92 or that are to be handled in free zones or free warehouses, as defined in Article 4(15)(b) of Regulation (EEC) No 2913/92;

(b) food for the supply of the crew and passengers of international means of transport;

(c) feed and food ordered remotely (for example, by mail, by telephone or via the internet) and delivered to the consumer;

(d) feed intended for pets or horses and food carried by passengers and crew of international means of transport;

(e) specific conditions or exemptions concerning certain territories referred to in Article 3 of Regulation (EEC) No 2913/92, so as to take account of the natural constraints specific to those territories;

(f) the purpose of ensuring the consistency of decisions by competent authorities concerning feed and food from third countries within the framework of Article 19;

(g) consignments of Community origin that are returned from a third country;

(h) documents that must accompany consignments when samples have been taken.

CHAPTER VI

FINANCING OF OFFICIAL CONTROLS

Article 26

General principle

Member States shall ensure that adequate financial resources are available to provide the necessary staff and other resources for official controls by whatever means considered appropriate, including through general taxation or by establishing fees or charges.

Article 27

Fees or charges

1. Member States may collect fees or charges to cover the costs occasioned by official controls.

2. However, as regards the activities referred to in Annex IV, section A, and Annex V, section A, Member States shall ensure the collection of a fee.

3. Without prejudice to paragraphs 4 and 6, fees collected as regards the specific activities mentioned in Annex IV, section A and Annex V, section A shall not be lower than the minimum rates specified in Annex IV, section B and Annex V, section B. However, for a transitional period until 1 January 2008, as regards the activities referred to in Annex IV, section A, Member States may continue to use the rates currently applied pursuant to Directive 85/73/EEC.

The rates in Annex IV, Section B and Annex V, Section B shall be updated at least every two years, in accordance with the procedure referred to in Article 62(3), in particular to take account of inflation.

4. Fees collected for the purposes of official controls in accordance with paragraph 1 or 2:

(a) shall not be higher than the costs borne by the responsible competent authorities in relation to the items listed in Annex VI;

and

(b) may be fixed at a flat-rate on the basis of the costs borne by the competent authorities over a given period of time or, where applicable, at the amounts fixed in Annex IV, section B or in Annex V, section B.

5. In setting the fees Member States shall take into consideration:

(a) the type of business concerned and relevant risk factors;

(b) the interests of businesses with a low throughput;

(c) traditional methods used for production, processing and distribution;

(d) the needs of businesses located in regions subject to particular geographical constraints.

6. When, in view of own-check and tracing systems implemented by the feed or food business as well as of the level of compliance found during official controls, for a certain type of feed or food or activities, official controls are carried out with a reduced frequency or to take account of the criteria referred to in paragraph 5(b) to (d), Member States may set the official control fee below the minimum rates referred to in paragraph 4(b), provided that the Member State concerned provides the Commission with a report specifying:

(a) the type of feed or food or activity concerned;

(b) the controls performed in the feed and food business concerned;

and

(c) the method for calculating the reduction of the fee.

7. When the competent authority carries out several official controls at the same time in a single establishment, it shall consider these controls as a single activity and charge a single fee.

8. Fees relating to import controls are to be paid by the operator or his representative to the competent authority in charge of import controls.

9. Fees shall not directly or indirectly be refunded, unless unduly collected.

10. Without prejudice to the costs deriving from the expenses referred to in Article 28, Member States shall not collect any fees other than those referred to in this Article for the implementation of this Regulation.

11. Operators or other relevant businesses or their representatives shall receive proof of their payment of fees.

12. The Member States shall make public the method of calculation of fees and communicate it to the Commission. The Commission shall examine whether the fees comply with the requirements of this Regulation.

Article 28

Expenses arising from additional official controls

When the detection of non-compliance leads to official controls that exceed the competent authority's normal control activities, the competent authority shall charge the operators responsible for the non-compliance, or may charge the operator owning or keeping the goods at the time when the additional official controls are carried out, for the expenses arising from the additional official controls. Normal control activities are the routine control activities required under Community or national law and, in particular, those described in the plan provided for in Article 41. Activities that exceed normal control activities include the taking and analysis of samples as well as other controls that are required to check the extent of a problem, to verify whether corrective action has been taken, or to detect and/or substantiate non-compliance.

Article 29

Level of expenses

When setting the level of expenses referred to in Article 28, account shall be taken of the principles laid down in Article 27.

CHAPTER VII

OTHER PROVISIONS

Article 30

Official certification

1. Without prejudice to requirements concerning official certification adopted for animal health or animal welfare purposes, requirements may be adopted, in accordance with the procedure referred to in Article 62(3), concerning:

(a) the circumstances in which official certification is required;

(b) model certificates;

(c) qualifications of the certifying staff;

(d) the principles to be respected to ensure reliable certification, including electronic certification;

(e) the procedures to be followed in case of withdrawal of certificates and for replacement certificates;

(f) consignments that are split into smaller consignments or that are mixed with other consignments;

(g) documents that must follow goods after official controls have been carried out.

2. Where official certification is required, it shall be ensured that:

(a) a link exists between the certificate and the consignment;

(b) the information in the certificate is accurate and authentic.

3. A single model certificate shall, where appropriate, combine requirements concerning the official certification of feed and food and other requirements for official certification.

Article 31

Registration/approval of feed and food business establishments

1. (a) Competent authorities shall establish procedures for feed and food business operators to follow when applying for the registration of their establishments in accordance with Regulation (EC) No 852/2004, Directive 95/69/EC or with the future regulation on feed hygiene;

(b) They shall draw up and keep up to date a list of feed and food business operators which have been registered. Where such a list already exists for other purposes, it may also be used for the purposes of this Regulation.

2. (a) Competent authorities shall establish procedures for feed and food business operators to follow when applying for the approval of their establishments in accordance with Regulation (EC) No 852/2004, Regulation (EC) No 854/2004, Directive 95/69/EC or with the future regulation on feed hygiene.

(b) Upon receipt of an application for approval from a feed or food business operator, the competent authority shall make an on-site visit.

(c) It shall approve an establishment for the activities concerned only if the feed or food business operator has demonstrated that it complies with the relevant requirements of feed or food law.

(d) The competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new official control of the establishment, carried out within three months of granting conditional approval, that the establishment meets the other relevant requirements of feed or food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.

(e) The competent authority shall keep the approval of establishments under review when carrying out official controls. If the competent authority identifies serious deficiencies or has to stop production at an establishment repeatedly and the feed or food business operator is not able to provide adequate guarantees regarding future production, the competent authority shall initiate procedures to withdraw the establishment's approval. However, the competent authority may suspend an establishment's approval if the feed or food business operator can guarantee that it will resolve deficiencies within a reasonable time;

(f) The competent authorities shall maintain up-to--date lists of approved establishments and make them available to other Member States and to the public in a manner that may be specified in accordance with the procedure referred to in Article 62(3).

TITLE III

REFERENCE LABORATORIES

Article 32

Community reference laboratories

1. The Community reference laboratories for feed and food referred to in Annex VII shall be responsible for:

(a) providing national reference laboratories with details of analytical methods, including reference methods;

(b) coordinating application by the national reference laboratories of the methods referred to in (a), in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;

(c) coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;

(d) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;

(e) providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;

(f) collaborating with laboratories responsible for analysing feed and food in third countries.

2. The Community reference laboratories in the animal health sector shall be responsible for:

(a) coordinating the methods employed in the Member States for diagnosing diseases;

(b) assisting actively in the diagnosis of disease outbreaks in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;

(c) facilitating the initial or further training of experts in laboratory diagnosis with a view to the harmonisation of diagnostic techniques throughout the Community;

(d) collaborating, as regards methods of diagnosing animal diseases falling within their competence, with the competent laboratories in third countries where those diseases are prevalent:

(e) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;

3. Article 12(2) and (3) shall apply to Community reference laboratories.

4. Community reference laboratories shall fulfil the following requirements. They must:

(a) have suitably qualified staff with adequate training in diagnostic and analytical techniques applied in their area of competence;

(b) possess the equipment and products needed to carry out the tasks assigned to them;

(c) have an appropriate administrative infrastructure;

(d) ensure that their staff respect the confidential nature of certain subjects, results or communications;

(e) have sufficient knowledge of international standards and practices;

(f) have available, if appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;

(g) take account of research activities at national and Community level;

(h) have trained personnel available for emergency situations occurring within the Community.

5. Other Community reference laboratories relevant to the areas referred to in Article 1 may be included in Annex VII in accordance with the procedure referred to in Article 62(3). In accordance with the same procedure, Annex VII may be updated.

6. Additional responsibilities and tasks for Community reference laboratories may be laid down in accordance with the procedure referred to in Article 62(3).

7. Community reference laboratories may be granted a Community financial contribution in accordance with Article 28 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field [1].

8. Community reference laboratories may be subject to Community controls to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements or tasks for which they have been designated, necessary measures may be taken in accordance with the procedure referred to in Article 62(3).

9. Paragraphs 1 to 7 shall apply without prejudice to more specific rules, and in particular Chapter VI of Regulation (EC) No 999/2001 and Article 14 of Directive 96/23/EC.

Article 33

National reference laboratories

1. Member States shall arrange for the designation of one or more national reference laboratories for each Community reference laboratory referred to in Article 32. A Member State may designate a laboratory situated in another Member State or European Free Trade Association (EFTA) Member and a single laboratory may be the national reference laboratory for more than one Member State.

2 These national reference laboratories shall:

(a) collaborate with the Community reference laboratory in their area of competence;

(b) coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Article 11;

(c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;

(d) ensure the dissemination to the competent authority and official national laboratories of information that the Community reference laboratory supplies;

(e) provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53;

(f) be responsible for carrying out other specific duties provided for in accordance with the procedure referred to in Article 62(3), without prejudice to existing additional national duties.

3. Article 12(2) and (3) shall apply to national reference laboratories.

4. Member States shall communicate the name and address of each national reference laboratory to the Commission, the relevant Community reference laboratory and other Member States.

5. Member States that have more than one national reference laboratory for a Community reference laboratory must ensure that these laboratories work closely together, so as to ensure efficient coordination between them, with other national laboratories and with the Community reference laboratory.

6. Additional responsibilities and tasks for national reference laboratories may be laid down in accordance with the procedure referred to in Article 62(3).

7. Paragraphs 1 to 5 shall apply without prejudice to more specific rules and in particular Chapter VI of Regulation (EC) No 999/2001 and Article 14 of Directive 96/23/EC.

[1] OJ L 224, 18.8.1990, p. 19. Decision as last amended by Regulation (EC) No 806/2003.

TITLE IV

ADMINISTRATIVE ASSISTANCE AND COOPERATION IN THE AREAS OF FEED AND FOOD

Article 34

General principles

1. Where the outcome of official controls on feed and food requires action in more than one Member State, competent authorities in the Member States concerned shall provide each other with administrative assistance.

2. Competent authorities shall provide administrative assistance upon request, or spontaneously when the course of investigations so requires. Administrative assistance may include, where appropriate, participation in on-the-spot controls that the competent authority of another Member State carries out.

3. Articles 35 to 40 shall not prejudice national rules applicable to the release of documents that are the object of, or are related to, court proceedings, or rules aimed at the protection of natural or legal persons' commercial interests.

Article 35

Liaison bodies

1. Each Member State shall designate one or more liaison bodies to liaise as appropriate with other Member States' liaison bodies. The role of liaison bodies shall be to assist and coordinate communication between competent authorities and, in particular, the transmission and reception of requests for assistance.

2. Member States shall inform the Commission and other Member States of all the relevant details of their designated liaison bodies, and of any modification of these details.

3. Without prejudice to paragraph 1, the designation of liaison bodies shall not preclude direct contacts, exchange of information or cooperation between the staff of competent authorities in different Member States.

4. The competent authorities to which Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure correct application of the legislation on veterinary and zootechnical matters [1] applies, shall liaise as appropriate with the authorities operating under this title.

Article 36

Assistance on request

1. Upon receiving a reasoned request, the requested competent authority shall ensure that the requesting competent authority is provided with all necessary information and documents enabling the latter to verify compliance with feed and food law within its jurisdiction. For that purpose, the requested competent authority shall arrange for the conduct of any administrative enquiries necessary to obtain such information and documents.

2. Information and documents provided pursuant to paragraph 1 shall be forwarded without undue delay. Documents may be transmitted in their original form or copies may be provided.

3. By agreement between the requesting authority and the requested authority, staff designated by the requesting authority may be present during administrative enquiries.

Such enquiries shall always be carried out by staff of the requested authority.

The requesting authority's staff may not, on their own initiative, exercise the powers of enquiry conferred on officials of the requested authority. They shall, however, have access to the same premises and documents as the latter, through their intermediary, and for the sole purpose of the administrative enquiry being carried out.

4. Staff of the requesting authority present in another Member State in accordance with paragraph 3 shall at all times be able to produce written authority stating their identity and their official capacity.

[1] OJ L 351, 2.12.1989, p. 34.

Article 37

Assistance without request

1. When a competent authority becomes aware of non-compliance, and if such non-compliance may have implications for another Member State or States, it shall pass such information to the other Member State(s) without prior request and without delay.

2. Member States receiving such information shall investigate the matter and inform the Member State that provided the information of the results of this investigation and, where appropriate, of any measures taken.

Article 38

Assistance in the event of non-compliance

1. If, during an official control carried out at the place of destination of the goods, or during their transport, the competent authority of the Member State of destination establishes that the goods do not comply with feed or food law in such a way as to create a risk to human or animal health or to constitute a serious infringement of feed or food law, it shall contact the competent authority of the Member State of dispatch without delay.

2. The competent authority of the Member State of dispatch shall investigate the matter, take all necessary measures and notify the competent authority of the Member State of destination of the nature of the investigations and official controls carried out, the decisions taken and the reasons for such decisions.

3. If the competent authority of the Member State of destination has reason to believe that such measures are inadequate, the two Member States' competent authorities shall together seek ways and means of remedying the situation including, if appropriate, a joint on-the-spot inspection carried out in accordance with Article 36(3) and (4). They shall inform the Commission if they are not able to agree on appropriate measures.

Article 39

Relations with third countries

1. When a competent authority receives information from a third country indicating non-compliance and/or a risk to human or animal health, that authority shall pass that information on to competent authorities in other Member States if it considers that they might be interested in it or if they request it. It shall also communicate such information to the Commission whenever it is of relevance at Community level.

2. If the third country has given a legal undertaking to provide the assistance required to gather evidence of the irregular nature of transactions that are or appear to be contrary to the relevant feed and food law, information obtained under this Regulation may be communicated to that third country, with the consent of the competent authorities that supplied the information, in accordance with laws applying to the communication of personal data to third countries.

Article 40

Coordinated assistance and follow-up by the Commission

1. The Commission shall coordinate without delay the action undertaken by Member States when it, further to information received from Member States or from other sources, becomes aware of activities that are, or appear to be, contrary to feed or food law and are of particular interest at Community level, and in particular when:

(a) such activities have, or might have, ramifications in several Member States;

(b) it appears that similar activities have been carried out in several Member States;

or

(c) Member States are unable to agree on appropriate action to address non-compliance.

2. When official controls at destination show repeated non-compliance or other risks to humans, plants or animals from feed or food, either directly or through the environment, the competent authority of the Member State of destination shall inform the Commission and the competent authorities of the other Member States without delay.

3. The Commission may:

(a) in collaboration with the Member State concerned, send an inspection team to carry out an official control on the spot;

(b) request that the competent authority of the Member State of dispatch intensify relevant official controls and report on the action and measures taken.

4. Where the measures provided for in paragraphs 2 and 3 are taken to deal with repeated non-compliance by a feed or food business, the competent authority shall charge any expenses arising from such measures to the business in question.

TITLE V

CONTROL PLANS

Article 41

Multi-annual national control plans

In order to ensure the effective implementation of Article 17(2) of Regulation (EC) No 178/2002, of animal health and animal welfare rules and of Article 45 of this Regulation, each Member State shall prepare a single integrated multi-annual national control plan.

Article 42

Principles for the preparation of multi-annual national control plans

1. Member States shall:

(a) implement the plan referred to in Article 41 for the first time no later than 1 January 2007;

and

(b) regularly update it in the light of developments;

and

(c) provide the Commission with the latest version of the plan on request.

2. Each multi-annual national control plan shall contain general information on the structure and organisation of the systems of feed and food control, and of animal health and animal welfare control in the Member State concerned, in particular on:

(a) the strategic objectives of the plan and on how the prioritisation of controls and allocation of resources reflect these objectives;

(b) the risk categorisation of the activities concerned;

(c) the designation of competent authorities and their tasks at central, regional and local level, and on resources available to these authorities;

(d) the general organisation and management of official controls at national, regional and local level, including official controls in individual establishments;

(e) control systems applied to different sectors and coordination between the different services of competent authorities responsible for official controls in these sectors;

(f) where appropriate, the delegation of tasks to control bodies;

(g) methods to ensure compliance with the operational criteria of Article 4(2);

(h) the training of staff performing official controls referred to in Article 6;

(i) the documented procedures referred to in Articles 8 and 9;

(j) the organisation and operation of contingency plans for animal or food-borne disease emergencies, feed and food contamination incidents and other human health risks;

(k) the organisation of cooperation and mutual assistance.

3. Multi-annual national control plans may be adjusted during their implementation. Amendments may be made in the light of, or in order to take account of, factors including:

(a) new legislation;

(b) the emergence of new diseases or other health risks;

(c) significant changes to the structure, management or operation of the competent national authorities;

(d) the results of Member States' official controls;

(e) the results of Community controls carried out in accordance with Article 45;

(f) any amendment of the guidelines referred to in Article 43;

(g) scientific findings;

(h) the outcome of audits performed by a third country in a Member State.

Article 43

Guidelines for multi-annual national control plans

1. The multi-annual national control plans referred to in Article 41 shall take account of guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2). These guidelines shall in particular:

(a) promote a consistent, comprehensive and integrated approach to official controls of feed and food, animal health and animal welfare legislation, and embrace all sectors and all stages of the feed and food chain, including import and introduction;

(b) identify risk-based priorities and criteria for the risk categorisation of the activities concerned and the most effective control procedures;

(c) identify other priorities and the most effective control procedures;

(d) identify the stages of production, processing and distribution of feed and food, including the use of feed, which will provide the most reliable and indicative information about compliance with feed and food law;

(e) encourage the adoption of best practices at all levels of the control system;

(f) encourage the development of effective controls on traceability systems;

(g) provide advice on the development of systems to record the performance and results of control actions;

(h) reflect relevant international bodies' standards and recommendations regarding the organisation and operation of official services;

(i) lay down criteria for the conduct of the audits referred to in Article 4(6);

(j) lay down the structure of, and information to be included in, the annual reports required in Article 44;

(k) indicate the main performance indicators to be applied in assessing multi-annual national control plans.

2. Where necessary, the guidelines shall be adapted in the light of the analysis of annual reports that Member States submit in accordance with Article 44 or Community controls carried out in accordance with Article 45.

Article 44

Annual reports

1. One year after starting the implementation of multi-annual national control plans, and subsequently every year, Member States shall submit to the Commission a report indicating:

(a) any amendments made to multi-annual national control plans to take account of the factors referred to in Article 42(3);

(b) the results of controls and audits conducted in the previous year under the provisions of the multi-annual national control plan;

(c) the type and number of cases of non-compliance identified;

(d) actions to ensure the effective operation of multi-annual national control plans, including enforcement action and its results.

2. In order to promote the consistent presentation of this report and in particular of the results of official controls, the information referred to in paragraph 1 shall take account of guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2).

3. Member States shall finalise their reports and transmit them to the Commission, within six months of the end of the year to which the reports relate.

4. In the light of the reports referred to in paragraph 1, the outcome of Community controls carried out in accordance with Article 45 and any other relevant information, the Commission shall establish an annual report on the overall operation of official controls in Member States. This report may, where appropriate, include recommendations on:

(a) possible improvements to official control and audit systems in Member States, including their scope, management and implementation;

(b) specific control actions concerning sectors or activities, regardless of whether these are covered by multi-annual national control plans;

(c) coordinated plans aiming at addressing issues of particular interest.

5. Multi-annual national control plans and the related guidelines shall, where appropriate, be adapted on the basis of the conclusions and recommendations contained in the Commission's report.

6. The Commission shall submit its report to the European Parliament and the Council and make it available to the public.

TITLE VI

COMMUNITY ACTIVITIES

CHAPTER I

COMMUNITY CONTROLS

Article 45

Community controls in Member States

1. Commission experts shall carry out general and specific audits in Member States. The Commission may appoint experts from Member States to assist its own experts. General and specific audits shall be organised in cooperation with Member States' competent authorities. Audits shall be carried out on a regular basis. Their main purpose shall be to verify that, overall, official controls take place in Member States in accordance with the multi-annual national control plans referred to in Article 41 and in compliance with Community law. For this purpose, and in order to facilitate the efficiency and effectiveness of the audits, the Commission may, in advance of carrying out such audits, request that the Member States provide, as soon as possible, up-to-date copies of national control plans.

2. Specific audits and inspections in one or more specific areas may supplement general audits. These specific audits and inspections shall in particular serve to:

(a) verify the implementation of the multi-annual national control plan, feed and food law and animal health and animal welfare legislation and may include, as appropriate, on-the-spot inspections of official services and of facilities associated with the sector being audited;

(b) verify the functioning and organisation of competent authorities;

(c) investigate important or recurring problems in Member States;

(d) investigate emergency situations, emerging problems or new developments in Member States.

3. The Commission shall report on the findings of each control carried out. Its report shall, if appropriate, contain recommendations for Member States on the improvement of compliance with feed and food law and animal health and animal welfare rules. The Commission shall make its reports publicly available. In the case of reports on controls carried out in a Member State, the Commission shall provide the relevant competent authority with a draft report for comments, take those comments into consideration in preparing the final report and publish the competent authority's comments together with the final report.

4. The Commission shall establish an annual control programme, communicate it to Member States in advance, and report on its results. The Commission may amend the programme to take account of developments in the fields of feed and food safety, animal health, animal welfare and plant health.

5. Member States shall:

(a) take appropriate follow-up action in the light of the recommendations resulting from Community controls;

(b) give all necessary assistance and provide all documentation and other technical support that Commission experts request to enable them to carry out controls efficiently and effectively;

(c) ensure that Commission experts have access to all premises or parts of premises and to information, including computing systems, relevant to the execution of their duties.

6. Detailed rules concerning Community controls in Member States may be drawn up or amended in accordance with the procedure referred to in Article 62(3).

Article 46

Community controls in third countries

1. Commission experts may carry out official controls in third countries in order to verify, on the basis of the information referred to in Article 47(1), the compliance or equivalence of third-country legislation and systems with Community feed and food law and Community animal health legislation. The Commission may appoint experts from Member States to assist its own experts. Such official controls shall have particular regard to:

(a) the legislation of the third country;

(b) the organisation of the third country's competent authorities, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively;

(c) the training of staff in the performance of official controls;

(d) the resources including diagnostic facilities available to competent authorities;

(e) the existence and operation of documented control procedures and control systems based on priorities;

(f) where applicable, the situation regarding animal health, zoonoses and plant health, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal and plant diseases;

(g) the extent and operation of official controls on imports of animals, plants and their products;

(h) the assurances which the third country can give regarding compliance with, or equivalence to, Community requirements.

2. In order to facilitate the efficiency and effectiveness of the controls in a third country, the Commission may, in advance of carrying out such controls, request that the third country concerned provide the information referred to in Article 47(1) and, where appropriate, the written records on the implementation of such controls.

3. The frequency of Community controls in third countries shall be determined on the basis of:

(a) a risk assessment of the products exported to the Community;

(b) the provisions of Community legislation;

(c) the volume and nature of imports from the country concerned;

(d) the results of controls that the Commission services or other inspection bodies have already carried out;

(e) the results of import controls and of any other controls that competent authorities of Member States have carried out;

(f) information received from the European Food Safety Authority or similar bodies;

(g) information received from internationally recognised bodies such as the World Health Organisation (WHO), the Codex Alimentarius Commission and the World Organisation for Animal Health (OIE), or from other sources;

(h) evidence of emerging disease situations or other circumstances that might result in live animals, live plants or feed or food imported from a third country presenting health risks;

(i) the need to investigate or respond to emergency situations in individual third countries.

The criteria for determining risk for the purpose of the risk assessment referred to in point (a) shall be decided in accordance with the procedure referred to in Article 62(3).

4. The procedure and detailed rules for controls in third countries may be determined or amended in accordance with the procedure referred to in Article 62(3).

They shall include, in particular, procedures for and detailed rules on:

(a) controls in third countries in the context of a bilateral agreement;

(b) controls in other third countries.

According to the same procedure, charges for the abovementioned controls may be established on a reciprocal basis.

5. If, during a Community control, a serious risk to human or animal health is identified, the Commission shall immediately take any necessary emergency measures in accordance with Article 53 of Regulation (EC) No 178/2002 or safeguard provisions in other relevant Community legislation.

6. The Commission shall report on the findings of each Community control carried out. Its report shall, if appropriate, contain recommendations. The Commission shall make its reports publicly available.

7. The Commission shall communicate its programme of controls in third countries to Member States in advance and report on the results. It may amend the programme to take account of developments in the fields of feed and food safety, animal health and plant health.

CHAPTER II

IMPORT CONDITIONS

Article 47

General import conditions

1. The Commission shall be responsible for requesting third countries intending to export goods to the Community to provide the following accurate and up-to-date information on the general organisation and management of sanitary control systems:

(a) any sanitary or phytosanitary regulations adopted or proposed within its territory;

(b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures operated within its territory;

(c) risk-assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;

(d) where appropriate, the follow-up given to the recommendations made pursuant to controls referred to in Article 46.

2. The information referred to in paragraph 1 shall be proportionate to the nature of the goods and may take account of the specific situation and structure of the third country and the nature of the products exported to the Community. Its scope shall cover at least the goods intended to be exported to the Community.

3. The information referred to in paragraphs 1 and 2 may also relate to:

(a) results of the national controls carried out on goods intended to be exported to the Community;

(b) important changes which have been made to the structure and functioning of the relevant control systems, in particular to meet Community requirements or recommendations.

4. Where a third country does not provide such information or where such information is inadequate, specific import conditions may be fixed in accordance with the procedure referred to in Article 62(3) on a case by case and strictly temporary basis following consultations with the third country concerned.

5. Guidelines, specifying how the information referred to in paragraphs 1, 2 and 3 shall be drawn up and presented to the Commission, as well as transitional measures allowing time for third countries to prepare this information shall be established in accordance with the procedure referred to in Article 62(2).

Article 48

Specific import conditions

1. To the extent that the conditions and detailed procedures to be respected when importing goods from third countries or their regions are not provided for by Community law and in particular by Regulation (EC) No 854/2004, they shall, if necessary, be laid down in accordance with the procedure referred to in Article 62(3).

2. The conditions and detailed procedures referred to in paragraph 1 may include:

(a) the establishment of a list of third countries from which specific products may be imported into one of the territories referred to in Annex I;

(b) the establishment of models of certificates accompanying consignments;

(c) special import conditions, depending on the type of product or animal and the possible risks associated therewith.

3. Third countries shall appear on the lists referred to in paragraph 2(a) only if their competent authorities provide appropriate guarantees as regards compliance or equivalence with Community feed and food law and animal health rules.

4. When drawing up or updating lists, particular account shall be taken of the following criteria:

(a) the third country's legislation in the sector concerned;

(b) the structure and organisation of the competent authority of the third country and its control services, as well as the powers available to it/them and the guarantees that can be provided with regard to the implementation of the legislation concerned;

(c) the existence of adequate official controls;

(d) the regularity and rapidity of information supplied by the third country on the presence of hazards in feed and food, and in live animals;

(e) the guarantees given by a third country that:

(i) conditions applied to the establishments from which feed and food may be imported in the Community comply with or are equivalent to the requirements in Community feed and food law;

(ii) a list of such establishments is drawn up and kept up to date;

(iii) the list of establishments and its updated versions are communicated to the Commission without delay;

(iv) the establishments are the subject of regular and effective controls by the competent authority of the third country.

5. When adopting the special import conditions referred to in paragraph 2(c), account shall be taken of information that the third countries concerned have provided and, where necessary, the results of Community controls carried out in such third countries. Special import conditions may be established for a single product or for a group of products. They may apply to a single third country, to regions of a third country, or to a group of third countries.

Article 49

Equivalence

1. Following the implementation of an equivalence agreement, or a satisfactory audit, a decision may be taken, in accordance with the procedure referred to in Article 62(3), recognising that measures that third countries or their regions apply in specific areas offer guarantees equivalent to those applied in the Community, if the third countries supply objective proof in this respect.

2. The decision referred to in paragraph 1 shall set out the conditions governing the imports from that third country or region of a third country.

The conditions may include:

(a) the nature and content of the certificates that must accompany the products;

(b) specific requirements applicable to importation into the Community;

(c) where necessary, procedures for drawing up and amending lists of regions or establishments from which imports are permitted.

3. The decision referred to in paragraph 1 shall be repealed in accordance with the same procedure and without delay where any of the conditions for recognition of equivalence established at the time of its adoption cease to be fulfilled.

Article 50

Support for developing countries

1. In accordance with the procedure referred to in Article 62(3) the following measures may be adopted and maintained so long as they have a demonstrable effect in ensuring that developing countries are able to comply with the provisions of this Regulation:

(a) a phased introduction of the requirements referred to in Articles 47 and 48 for products exported to the Community. Progress in meeting these requirements shall be evaluated and taken into account in determining the need for specified time-limited exemptions in whole or in part from the requirements. The phased introduction shall also take into account the progress in building the institutional capacity referred to in paragraph 2;

(b) assistance with providing the information referred to in Article 47, if necessary by Community experts;

(c) the promotion of joint projects between developing countries and Member States;

(d) the development of guidelines to assist developing countries in organising official controls on products exported to the Community;

(e) sending Community experts to developing countries so as to assist in the organisation of official controls;

(f) the participation of control staff from developing countries in the training courses referred to in Article 51.

2. In the context of the Community's development cooperation policy, the Commission shall promote support to developing countries with regard to feed and food safety in general and compliance with feed and food standards in particular, in order to build the institutional capacity required to meet the requirements referred to in Articles 5, 12, 47 and 48.

CHAPTER III

TRAINING OF CONTROL STAFF

Article 51

Training of control staff

1. The Commission may organise training courses for the staff of the competent authorities of Member States responsible for the official controls referred to in this Regulation. These training courses shall serve to develop a harmonised approach to official controls in Member States. They may include in particular training on:

(a) Community feed and food law and animal health and animal welfare rules;

(b) control methods and techniques, such as the auditing of systems that operators design to comply with feed and food law, animal health and animal welfare rules;

(c) controls to be carried out on goods imported into the Community;

(d) feed and food production, processing and marketing methods and techniques.

2. The training courses referred to in paragraph 1 may be open to participants from third countries, in particular developing countries.

3. Detailed rules for the organisation of training courses may be laid down in accordance with the procedure referred to in Article 62(3).

CHAPTER IV

OTHER COMMUNITY ACTIVITIES

Article 52

Third-country controls in Member States

1. Commission experts may, at the request of and in cooperation with the competent authorities of Member States, assist Member States during controls that third countries carry out.

2. In such cases, Member States in whose territory a third country is to carry out a control shall inform the Commission about the planning, scope, documentation and any other relevant information enabling the Commission to take part effectively in the control.

3. The Commission's assistance shall serve in particular to:

(a) clarify Community feed and food law and animal health and animal welfare rules;

(b) provide information and data available at Community level that may be useful for the control carried out by the third country;

(c) ensure uniformity with regard to controls carried out by third countries.

Article 53

Coordinated control plans

The Commission may recommend coordinated plans in accordance with the procedure referred to in Article 62(2). These plans shall be:

(a) organised annually in accordance with a programme;

and

(b) where considered necessary, organised on an ad hoc basis, in particular with a view to establishing the prevalence of hazards in feed, food or animals.

TITLE VII

ENFORCEMENT MEASURES

CHAPTER I

NATIONAL ENFORCEMENT MEASURES

Article 54

Action in case of non-compliance

1. When the competent authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.

2. Such action shall include, where appropriate, the following measures:

(a) the imposition of sanitation procedures or any other action deemed necessary to ensure the safety of feed or food or compliance with feed or food law, animal health or animal welfare rules;

(b) the restriction or prohibition of the placing on the market, import or export of feed, food or animals;

(c) monitoring and, if necessary, ordering the recall, withdrawal and/or destruction of feed or food;

(d) the authorisation to use feed or food for purposes other than those for which they were originally intended;

(e) the suspension of operation or closure of all or part of the business concerned for an appropriate period of time;

(f) the suspension or withdrawal of the establishment's approval;

(g) the measures referred to in Article 19 on consignments from third countries;

(h) any other measure the competent authority deems appropriate.

3. The competent authority shall provide the operator concerned, or a representative, with:

(a) written notification of its decision concerning the action to be taken in accordance with paragraph 1, together with the reasons for the decision;

and

(b) information on rights of appeal against such decisions and on the applicable procedure and time limits.

4. Where appropriate, the competent authority shall also notify the competent authority of the Member State of dispatch of its decision.

5. All expenditure incurred pursuant to this Article shall be borne by the responsible feed and food business operator.

Article 55

Sanctions

1. Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other Community provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

2. Member States shall notify the provisions applicable to infringements of feed and food law and any subsequent amendment to the Commission without delay.

CHAPTER II

COMMUNITY ENFORCEMENT MEASURES

Article 56

Safeguard measures

1. Measures shall be taken under the procedures provided for in Article 53 of Regulation (EC) No 178/2002 if:

(a) the Commission has evidence of a serious failure in a Member State's control systems;

and

(b) such failure may constitute a possible and widespread risk for human health, animal health or animal welfare, either directly or through the environment.

2 Such measures shall be adopted only after:

(a) Community controls have shown and reported non-compliance with Community legislation;

and

(b) the Member State concerned has failed to correct the situation upon request and within the time limit set by the Commission.

TITLE VIII

ADAPTATION OF COMMUNITY LEGISLATION

Article 57

Amendment of Directive 96/23/EC

Directive 96/23/EC is hereby amended as follows:

1. Article 14(2) is replaced by the following:

'2 The Community reference laboratories shall be those referred to in the relevant part of Annex VII of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (*).

(*) OJ L 165, 30.4.2004, p. 1.'

2. In Article 30, the part of paragraph 1 beginning 'Where such additional checks demonstrate…' and ending '…or to use it for other purposes authorised by Community legislation, without indemnity or compensation', is replaced by the following:

'Where checks demonstrate the presence of unauthorised substances or products or when maximum limits have been exceeded, the provisions of Articles 19 to 22 of Regulation (EC) No 882/2004 shall apply.'

3. Annex V is deleted.

Article 58

Amendment of Directive 97/78/EC

Directive 97/78/EC is hereby amended as follows:

1. Article 1 is replaced by the following:

'Veterinary checks on products from third countries introduced into one of the territories listed in Annex I shall be carried out by Member States in accordance with this Directive and with Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (*).

(*) OJ L 165, 30.4.2004, p. 1.'

2. Article 2(2)(a) is replaced by the following:

'(a) "products" means the products of animal origin referred to in Directives 89/662/EEC and 90/425/EEC, in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption (*), in Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (**) and in Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (***); it also includes the plant products referred to in Article 19.

(*) OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 808/2003 (OJ L 117, 13.5.2003, p. 1).

(**) OJ L 18, 23.1.2003, p. 11.

(***) OJ L 139, 30.4.2004.'

3. In Article 7(3), 'inspection fees referred to in Council Directive 85/73/EEC of 29 January 1985 on the financing of veterinary inspections and controls covered by Directives 89/662/EEC, 90/425/EEC, 90/675/EEC and 91/496/EEC (amended and consolidated)' is replaced by the following:

'inspection fees referred to in Regulation (EC) No 882/2004'.

4. In Article 10(1)(b), the following phrase is deleted: 'or, in the case of establishments approved in accordance with Council Decision 95/408/EC of 22 June 1995 on the conditions for drawing up, for an interim period, provisional lists of third-country establishments from which Member States are authorised to import certain products of animal origin, fishery products or live bivalve molluscs, from an establishment which has undergone either a Community or a national inspection.'

5. Article 12(9) is deleted.

6. Article 15(5) is deleted.

7. In Article 16, the following paragraph is inserted:

'4 Detailed rules for the introduction of products of animal origin for the supply of the crew and passengers of international means of transport, and for products of animal origin ordered remotely (for example, by mail, by telephone or via the internet) and delivered to the consumer, shall be laid down in accordance with Article 25 of Regulation (EC) No 882/2004.'

8. Article 21 is deleted.

9. Article 23 is deleted.

10. In Article 24(1), second indent, 'in accordance with Article 17(2)(a) and (b)' is replaced by 'in accordance with Article 17'.

Article 59

Amendment of Directive 2000/29/EC

The following Article is inserted in Directive 2000/29/EC:

'*Article 27a*

For the purpose of this Directive and without prejudice to Article 21 thereof, Articles 41 to 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (*) shall apply, as appropriate.

(*) OJ L 165, 30.4.2004, p. 1.'

Article 60

Amendment of Regulation (EC) No 854/2004

Regulation (EC) No 854/2004 is hereby amended as follows:

1. In Article 1, the following paragraph is added:

'1a. This Regulation shall apply in addition to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (*).

(*) OJ L 165, 30.4.2004, p. 1.'

2. In Article 2:

(a) in paragraph 1, subparagraphs (a), (b), (d) and (e) are deleted;

and

(b) the following subparagraph is added to paragraph 2:

'(b)(a) Regulation (EC) No 882/2004.'

3. In Article 3:

(a) paragraph 1 is replaced by the following:

'1. The competent authorities shall approve establishments when, and in the manner, specified in Article 31(2) of Regulation (EC) No 882/2004';

and

(b) paragraphs 4(a) and (b) and paragraph 6 are deleted.

4. Article 9 is deleted.

5. Article 10 is replaced with the following:

'*Article 10*

To ensure the uniform application of the principles and conditions laid down in Article 11 of Regulation (EC) No 178/2002 and Title VI, Chapter II, of Regulation (EC) No 882/2004 the procedures laid down in this Chapter shall apply.'

6. In Article 11:

(a) paragraph 2 is replaced by the following:

'2 A third country shall appear on such lists only if a Community control in that country has taken place and demonstrates that the competent authority provides appropriate guarantees as specified in Article 48(3) of Regulation (EC) No 882/2004. However, a third country may appear on such lists without a Community control having taken place if:

(a) the risk determined in accordance with Article 46(3)(a) of Regulation (EC) No 882/2004 does not warrant it;

and

(b) it is determined, when deciding to add a particular third country to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.'

(b) in paragraph 4, the introduction is replaced by the following:

'4 When drawing up or updating lists, particular account shall be taken of the criteria listed in Articles 46 and 48(3) of Regulation (EC) No 882/2004. Regard shall also be had to.';

and

(c) subparagraphs (b) to (h) of paragraph 4 are deleted.

7. Article 14(2)(b) is replaced by the following:

'(b) any specific import conditions established in accordance with Article 48 of Regulation (EC) No 882/2004.'

8. Article 18(17) to (20) are deleted.

Article 61

Repeal of Community acts

1. Directives 70/373/EEC, 85/591/EEC, 89/397/EEC, 93/99/EEC and 95/53/EC and Decisions 93/383/EEC, 98/728/EC and 1999/313/EC are hereby repealed with effect from 1 January 2006. Directive 85/73/EEC is hereby repealed with effect from 1 January 2008.

2. However, the implementing rules adopted on the basis of those acts, in particular those referred to in Annex VIII, shall remain in force in so far as they are not in contradiction with this Regulation, pending the adoption of the necessary provisions on the basis of this Regulation.

3. Reference to the repealed acts shall be construed as references to this Regulation.

TITLE IX

GENERAL PROVISIONS

Article 62

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002 or, where dealing with matters mainly relating to plant health, by the Standing Committee on plant health set up by Council Decision 76/894/EEC [1].

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be three months.

4. The Committee shall adopt its Rules of Procedure.

Article 63

Implementing and transitional measures

1. Implementing and transitional measures necessary to ensure the uniform application of this Regulation may be laid down in accordance with the procedure referred to in Article 62(3).

This applies in particular to:

(a) the delegation of control tasks to control bodies referred to in Article 5, where these control bodies were already in operation before the entry into force of this Regulation;

[1] OJ L 340, 9.12.1976, p. 25.

(b) any modification with regard to the standards referred to in Article 12(2);

(c) the non-compliance referred to in Article 28 which gives rise to expenses arising from additional official controls;

(d) expenditure incurred pursuant to Article 54;

(e) rules on microbiological, physical and/or chemical analysis in official controls, in particular in case of suspicion of risk and including the surveillance of the safety of products imported from third countries;

(f) defining what feed is to be considered as feed of animal origin for the purpose of this Regulation.

2. In order to take account of the specificity of Regulations (EEC) No 2092/91, (EEC) No 2081/92 and (EEC) No 2082/92, specific measures to be adopted in accordance with the procedure referred to in Article 62(3) may provide for the necessary derogations from and adjustments to the rules laid down in this Regulation.

Article 64

Amendment of Annexes and references to European standards

In accordance with the procedure referred to in Article 62(3):

1. the Annexes to this Regulation may be updated, except for Annex I, Annex IV and Annex V, without prejudice to Article 27(3), in particular in order to take account of administrative changes and scientific and/or technological progress;

2. the references to the European standards referred to in this Regulation may be updated in the event that CEN amends these references.

Article 65

Report to the European Parliament and the Council

1. The Commission shall, not later than 20 May 2007, submit a report to the European Parliament and the Council.

2. The report shall, in particular, review the experience gained from the application of this Regulation and consider in particular the following issues:

(a) re-evaluating the scope, in relation to animal health and animal welfare;

(b) ensuring that other sectors contribute to the financing of official controls by extending the list of activities referred to in Annex IV, section A and in Annex V, section A, and taking into account in particular the impact of the Community feed and food hygiene legislation after its adoption;

(c) setting updated minimum rates for fees referred to in Annex IV, section B and in Annex V, section B, taking into account in particular risk factors.

3 The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 66

Community financial support

1. The appropriations required for:

(a) the travel and subsistence expenses that Member States' experts incur as a result of the Commission appointing them to assist its experts as provided for in Articles 45(1) and 46(1);

(b) the training of control staff provided for in Article 51;

(c) the financing of other measures necessary to ensure the application of this Regulation,

shall be authorised each year in the framework of the budgetary procedure.

2. The measures referred to in paragraph 1(c) shall include in particular the organisation of conferences, the establishment of databases, the publication of information, the organisation of studies and the organisation of meetings to prepare the sessions of the Standing Committee on the Food Chain and Animal Health.

3. Technical support and a financial contribution from the Community for the organisation of the activities referred to in Article 50 may be granted within the limits of the human and financial resources available to the Commission.

TITLE X

FINAL PROVISION

Article 67

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2006.

However, Articles 27 and 28 shall apply from 1 January 2007.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 29 April 2004.

For the European Parliament
The President
P. COX

For the Council
The President
M. McDOWELL

ANNEX I

TERRITORIES REFERRED TO IN ARTICLE 2(15)

1. The territory of the Kingdom of Belgium
2. The territory of the Kingdom of Denmark with the exception of the Faroe Islands and Greenland
3. The territory of the Federal Republic of Germany
4. The territory of the Kingdom of Spain with the exception of Ceuta and Melilla
5. The territory of the Hellenic Republic
6. The territory of the French Republic
7. The territory of Ireland
8. The territory of the Italian Republic
9. The territory of the Grand Duchy of Luxembourg
10. The territory of the Kingdom of the Netherlands in Europe
11. The territory of the Portuguese Republic
12. The territory of the United Kingdom of Great Britain and Northern Ireland
13. The territory of the Republic of Austria
14. The territory of the Republic of Finland
15. The territory of the Kingdom of Sweden

ANNEX II

COMPETENT AUTHORITIES

CHAPTER I: SUBJECT MATTER FOR THE TRAINING OF STAFF PERFORMING OFFICIAL CONTROLS

1. Different control techniques, such as auditing, sampling and inspection

2. Control procedures

3. Feed and food law

4. The different stages of production, processing and distribution, and the possible risks for human health, and where appropriate for the health of animals and plants and for the environment

5. Assessment of non-compliance with feed and food law

6. Hazards in animal feed and food production

7. The evaluation of the application of HACCP procedures

8. Management systems such as quality assurance programmes that feed and food businesses operate and their assessment in so far as these are relevant for feed or food law requirements

9. Official certification systems

10. Contingency arrangements for emergencies, including communication between Member States and the Commission

11. Legal proceedings and implications of official controls

12. Examination of written, documentary material and other records, including those related to proficiency testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with feed or food law; this may include financial and commercial aspects

13. Any other area, including animal health and animal welfare, necessary to ensure that official controls are carried out in accordance with this Regulation.

CHAPTER II: SUBJECT AREAS FOR CONTROL PROCEDURES

1. The organisation of the competent authority and the relationship between central competent authorities and authorities to which they have delegated tasks to carry out official controls

2. The relationship between competent authorities and control bodies to which they have delegated tasks related to official controls

3. A statement on the objectives to be achieved

4. Tasks, responsibilities and duties of staff

5. Sampling procedures, control methods and techniques, interpretation of results and consequent decisions

6. Monitoring and surveillance programmes

7. Mutual assistance in the event that official controls require more than one Member State to take action

8. Action to be taken following official controls

9. Cooperation with other services or departments that may have relevant responsibilities

10. Verification of the appropriateness of methods of sampling, methods of analysis and detection tests

11. Any other activity or information required for the effective functioning of the official controls.

ANNEX III

CHARACTERISATION OF METHODS OF ANALYSIS

1. Methods of analysis should be characterised by the following criteria:

   (a) accuracy;

   (b) applicability (matrix and concentration range);

   (c) limit of detection;

   (d) limit of determination;

   (e) precision;

   (f) repeatability;

   (g) reproducibility;

   (h) recovery;

   (i) selectivity;

   (j) sensitivity;

   (k) linearity;

   (l) measurement uncertainty;

   (m) other criteria that may be selected as required.

2. The precision values referred to in 1(e) shall either be obtained from a collaborative trial which has been conducted in accordance with an internationally recognised protocol on collaborative trials (e.g. ISO 5725:1994 or the IUPAC International Harmonised Protocol) or, where performance criteria for analytical methods have been established, be based on criteria compliance tests. The repeatability and reproducibility values shall be expressed in an internationally recognised form (e.g. the 95 % confidence intervals as defined by ISO 5725:1994 or IUPAC). The results from the collaborative trial shall be published or freely available.

3. Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.

4. In situations where methods of analysis can only be validated within a single laboratory then they should be validated in accordance with e.g. IUPAC Harmonised Guidelines, or where performance criteria for analytical methods have been established, be based on criteria compliance tests.

5. Methods of analysis adopted under this Regulation should be edited in the standard layout for methods of analysis recommended by the ISO.

ANNEX IV

ACTIVITIES AND MINIMUM RATES FOR FEES OR CHARGES RELATED TO OFFICIAL CONTROLS IN RELATION TO COMMUNITY ESTABLISHMENTS

SECTION A: ACTIVITIES

1. The activities covered by Directives 89/662/EEC, 90/425/EEC, 93/119/EC and 96/23/EC for which Member States are currently collecting fees pursuant to Directive 85/73/EEC

2. The approval of feed establishments

SECTION B: MINIMUM RATES

Member States shall collect for controls relating to the following list of products, at least the corresponding minimum rates for fees or charges.

CHAPTER I

Minimum rates for fees or charges applicable to slaughter inspection

(a) beef meat	
— adult bovine animals:	5 EUR/animal
— young bovine animals:	2 EUR/animal
(b) solipeds and equidae:	3 EUR/animal
(c) pigmeat: animals of a carcase weight	
— of less than 25 kg:	0,5 EUR/animal
— equal to or greater than 25 kg:	1 EUR/animal
(d) sheepmeat and goatmeat: animals of a carcase weight	
— of less than 12 kg:	0,15 EUR/animal
— equal to or greater than 12 kg:	0,25 EUR/animal
(e) poultrymeat	
— poultry of genus Gallus and guinea fowl:	0,005 EUR/animal
— ducks and geese:	0,01 EUR/animal
— turkeys:	0,025 EUR/animal
— farmed rabbit meat:	0,005 EUR/animal.

CHAPTER II

Minimum rates for fees or charges applicable to cutting plants controls

Per tonne of meat:

— beef, veal, pig, solipeds/equidae, sheep and goatmeat:	2 EUR
— poultry and farmed rabbit meat:	1,5 EUR
— farmed and wild game meat:	
— small game birds and ground game:	EUR 1,5
— ratites meat (ostrich, emu, nandou):	EUR 3
— boars and ruminants:	EUR 2.

CHAPTER III

Minimum rates for fees or charges applicable to game processing houses

(a) small game birds:	0,005 EUR/animal
(b) small ground game:	0,01 EUR/animal
(c) ratites:	0,5 EUR/animal
(d) land mammals:	
— boar:	1,5 EUR/animal
— ruminants:	0,5 EUR/animal

CHAPTER IV

Minimum rates for fees or charges applicable to milk production

— EUR 1 per 30 tonnes

and

— EUR 0,5 per tonne, thereafter.

CHAPTER V

Minimum rates for fees or charges applicable to the producing and placing on the market of fishery products and aquaculture products

(a) first placing on the market of fishery and aquaculture products:

— 1 EUR/tonne for the first 50 tonnes in the month;

— 0,5 EUR/tonne thereafter.

(b) first sale in fish market

— 0,5 EUR/tonne for the first 50 tonnes in the month;

— 0,25 EUR/tonne thereafter.

(c) first sale in case of lack of or insufficient gradation for freshness and/or size in accordance with Regulations (EEC) No 103/76 and (EEC) No 104/76:

— 1 EUR/tonne for the first 50 tonnes in the month;

— 0,5 EUR/tonne thereafter.

The fees collected on the species referred to in Annex II to Commission Regulation (EEC) No 3703/85 must not exceed EUR 50 per consignment.

Member States will collect 0,5 EUR/tonne for the processing of fishery and aquaculture products.

ANNEX V

ACTIVITIES AND MINIMUM RATES FOR FEES OR CHARGES RELATED TO THE OFFICIAL CONTROLS OF GOODS AND LIVE ANIMALS INTRODUCED INTO THE COMMUNITY

SECTION A: ACTIVITIES OR CONTROLS

The activities covered by Directives 97/78/EC and 91/496/EEC for which Member States are currently collecting fees pursuant to Directive 85/73/EEC.

SECTION B: FEES OR CHARGES

CHAPTER I

Fees applicable to imported meat

The minimum fee rates for the official control on the import of a consignment of meat are fixed at:

— EUR 55 per consignment, up to six tonnes,

and

— EUR 9 per tonne, up to 46 tonnes, thereafter,

or

— EUR 420 per consignment, over 46 tonnes.

CHAPTER II

Fees applicable to imported fishery products

1. The minimum fee for the official control on the import of a consignment of fishery products is fixed at:

   — EUR 55 per consignment, up to six tonnes,

   and

   — EUR 9 per tonne, up to 46 tonnes, thereafter,

   or

   — EUR 420 per consignment, over 46 tonnes.

2. The above amount for the official control on the import of a consignment of fishery products, transported as break bulk shipment, shall be:

   — EUR 600 per vessel, with a cargo of fishery products up to 500 tonnes,

   — EUR 1 200 per vessel, with a cargo of fishery products up to 1 000 tonnes,

   — EUR 2 400 per vessel, with a cargo of fishery products up to 2 000 tonnes,

   — EUR 3 600 per vessel, with a cargo of fishery products of more than 2 000 tonnes.

3. In the case of fishery products caught in their natural environment directly landed by a fishing vessel flying the flag of a third country, the provisions laid down in Annex IV, Section B, Chapter V, point (a) shall apply.

CHAPTER III

Fees or charges applicable to meat products, poultrymeat, wild game meat, rabbit meat, farmed game meat, by-products and feed of animal origin

1. The minimum fee for the official control on the import of a consignment of products of animal origin other than those mentioned in Chapters I and II or a consignment of by-products of animal origin or a consignment of feed, is fixed at:

— EUR 55 per consignment, up to six tonnes,

and

— EUR 9 per tonne, up to 46 tonnes, thereafter,

or

— EUR 420 per consignment, over 46 tonnes.

2. The above amount for the official control on the import of a consignment of products of animal origin other than those mentioned in Chapters I and II, a consignment of by-products of animal origin or a consignment of feed transported as break bulk shipment, shall be:

— EUR 600 per vessel, with a cargo of products up to 500 tonnes,

— EUR 1 200 per vessel, with a cargo of products up to 1 000 tonnes,

— EUR 2 400 per vessel, with a cargo of products up to 2 000 tonnes,

— EUR 3 600 per vessel, with a cargo products of more than 2 000 tonnes.

CHAPTER IV

Fees applicable to transit through the community of goods and live animals

The amount of fees or charges for the official control on the transit of goods and live animals through the Community is fixed at a minimum level of EUR 30, increased by EUR 20 per quarter of an hour for every member of staff involved in the controls.

CHAPTER V

Fees applicable to imported live animals

1. The fee for the official control on the import of a consignment of live animals is fixed:

(a) for bovine animals, equidae, pigs, sheep, goats, poultry, rabbits and small game birds or ground game and the following land mammals: wild boar and ruminants, at:

— EUR 55 per consignment, up to six tonnes,

and

— EUR 9 per tonne, up to 46 tonnes, thereafter,

or

— EUR 420 per consignment, over 46 tonnes,

(b) for animals of other species at the actual cost of inspection expressed either per animal or per tonne imported, at:

— EUR 55 per consignment, up to 46 tonnes,

or

— EUR 420 per consignment, over 46 tonnes,

it being understood that this minimum does not apply to imports of species referred to in Commission Decision 92/432/EEC.

2. At the request of a Member State, accompanied by appropriate supporting documents and in accordance with the procedure laid down in Article 18 of Directive 89/662/EEC, a lower level of fees may be applied to imports from certain third countries.

ANNEX VI

CRITERIA TO BE TAKEN INTO CONSIDERATION FOR THE CALCULATION OF FEES

1. The salaries of the staff involved in the official controls

2. The costs for the staff involved in the official controls, including facilities, tools, equipment, training, travel and associated costs

3. The laboratory analysis and sampling costs

ANNEX VII

COMMUNITY REFERENCE LABORATORIES

I. **Community reference laboratories for feed and food**

1. Community reference laboratory for milk and milk products

Afssa-Lerhqa
F-94700 Maisons-Alfort

2. Community reference laboratories for the analysis and testing of zoonoses (salmonella)

Rijksinstituut voor Volksgezondheid en Milieu (RIVM)
3720 BA Bilthoven
The Netherlands

3. Community reference laboratory for the monitoring of marine biotoxins

Ministerio de Sanidad y Consumo
Vigo
Spain

4. Community reference laboratory for monitoring the viral and bacteriological contamination of bivalve molluscs

The laboratory of the Centre for Environment, Fisheries and Aquaculture Science, Weymouth, United Kingdom.

5. Community reference laboratories for residues

(a) For the residues listed in Annex I, Group A 1, 2, 3, 4, Group B 2 (d) and Group B 3 (d) to Council Directive 96/23/EC

Rijksinstituut voor Volksgezondheid en Milieu (RIVM)
3720 BA Bithoven
The Netherlands

(b) For the residues listed in Annex I, Group B 1 and B 3 (e) to Council Directive 96/23/EC and carbadox and olaquidonx

Laboratoires d'études et de recherches sur les médicaments vétérinaires et les désinfectants
AFSSA - Site de Fougères
BP 90203
France

(c) For the residues listed in Annex I, Group A 5 and Group B 2 (a), (b), (e) to Council Directive 96/23/EC

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Postfach 140162
D-53056 Bonn

(d) For the residues listed in Annex I, Group B 2 (c) and Group B 3 (a), (b), (c) to Council Directive 96/23/EC

Instituto Superiore di Sanità
I-00161 -Roma

6. Community reference laboratory for transmissible spongiform encephalopathies (TSEs)

The laboratory referred to in Annex X, Chapter B of Regulation (EC) No 999/2001

7. Community reference laboratory for additives for use in animal nutrition

The laboratory referred to in Annex II of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1]

8. Community reference laboratory for genetically modified organisms (GMOs)

The laboratory referred to in the Annex to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2].

9. Community reference laboratory for material intended to come into contact with foodstuffs

The Joint Research Centre of the Commission

II. **Community reference laboratories for animal health**

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[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 268, 18.10.2003, p. 1.

ANNEX VIII

IMPLEMENTING RULES THAT REMAIN IN FORCE PURSUANT TO ARTICLE 61

1. Implementing rules based on Directive 70/373/EEC on the introduction of Community methods of sampling and analysis for the official control of feedingstuffs

(a) First Commission Directive 71/250/EEC of 15 June 1971 establishing Community methods of analysis for the official control of feedingstuffs ([1])

(b) Second Commission Directive 71/393/EEC of 18 November 1971 establishing Community methods of analysis for the official control of feedingstuffs ([2])

(c) Third Commission Directive 72/199/EEC of 27 April 1972 establishing Community methods of analysis for the official control of feedingstuffs ([3])

(d) Fourth Commission Directive 73/46/EEC of 5 December 1972 establishing Community methods of analysis for the official control of feedingstuffs ([4])

(e) First Commission Directive 76/371/EEC of 1 March 1976 establishing Community methods of sampling for the official control of feedingstuffs ([5])

(f) Seventh Commission Directive 76/372/EEC of 1 March 1976 establishing Community methods of analysis for the official control of feedingstuffs ([6])

(g) Eighth Commission Directive 78/633/EEC of 15 June 1978 establishing Community methods of analysis for the official control of feedingstuffs ([7])

(h) Ninth Commission Directive 81/715/EEC of 31 July 1981 establishing Community methods of analysis for the official control of feedingstuffs ([8])

(i) Tenth Commission Directive 84/425/EEC of 25 July 1984 establishing Community methods of analysis for the official control of feedingstuffs ([9])

(j) Eleventh Commission Directive 93/70/EEC of 28 July 1993 establishing Community methods of analysis for the official control of feedingstuffs ([10])

(k) Twelfth Commission Directive 93/117/EC of 17 December 1993 establishing Community methods of analysis for the official control of feedingstuffs ([11])

(l) Commission Directive 98/64/EC of 3 September 1998 establishing Community methods of analysis for the determination of amino acids, crude oils and fats, and olaquindox in feedingstuffs ([12])

([1]) OJ L 155, 12.7.1971, p. 13. Directive as last amended by Commission Directive 1999/27/EC (OJ L 118, 6.5.1999, p. 36).
([2]) OJ L 279, 20.12.1971, p. 7. Directive as last amended by Commission Directive 98/64/EC (OJ L 257, 19.9.1998, p. 14).
([3]) OJ L 123, 29.5.1972, p. 6. Directive as last amended by Commission Directive 1999/79/EC (OJ L 209, 7.8.1999, p. 23).
([4]) OJ L 83, 30.3.1973, p. 21. Directive as last amended by Commission Directive 1999/27/EC.
([5]) OJ L 102, 15.4.1976, p. 1.
([6]) OJ L 102, 15.4.1976, p. 8. Directive as last amended by Commission Directive 94/14/EC (OJ L 94, 13.4.1994, p. 30).
([7]) OJ L 206, 29.7.1978, p. 43. Directive as last amended by Commission Directive 84/4/EEC (OJ L 15, 18.1.1984, p. 28).
([8]) OJ L 257, 10.9.1981, p. 38.
([9]) OJ L 238, 6.9.1984, p. 34.
([10]) OJ L 234, 17.9.1993, p. 17.
([11]) OJ L 329, 30.12.1993, p. 54.
([12]) OJ L 257, 19.9.1998, p. 14.

(m) Commission Directive 2003/126/EC of 23 December 2003 on the analytical method for the determination of constituents of animal origin for the official control of foodstuffs [1]

(n) Commission Directive 1999/27/EC of 20 April 1999 establishing Community methods of analysis for the determination of amprolium, diclazuril and carbadox in feedingstuffs [2]

(o) Commission Directive 1999/76/EC of 23 July 1999 establishing a Community method of analysis for the determination of lasalocid sodium in feedingstuffs [3]

(p) Commission Directive 2000/45/EC of 6 July 2000 establishing Community methods of analysis for the determination of vitamin A, vitamin E and tryptophan in feedingstuffs [4]

(q) Directive 2002/70/EC of 26 July 2002 establishing requirements for the determination of levels of dioxins and dioxin-like PCBs in feedingstuffs [5]

2. Implementing rules based on Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition

Commission Directive 98/68/EC of 10 September 1998 laying down the standard document referred to in Article 9(1) of Council Directive 95/53/EC and certain rules for checks at the introduction into the Community of feedingstuffs from third countries [6].

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(1) OJ L 339, 24.12.2003, p. 78.
(2) OJ L 118, 6.5.1999, p. 36.
(3) OJ L 207, 6.8.1999, p. 13.
(4) OJ L 174, 13.7.2000, p. 32.
(5) OJ L 209, 6.8.2002, p. 15.
(6) OJ L 261, 24.9.1998, p. 32.

ANNEX 8

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION RECOMMENDATION

of 4 October 2004

on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003

(Text with EEA relevance)

(2004/787/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, in particular the second indent of Article 211 thereof,

Whereas:

(1) Regulation (EC) No 1830/2003 of the European Parliament and of the Council, of 22 September 2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [1] sets up a system for the transmission and retention of information between operators at each stage of the placing on the market of products containing or consisting of genetically modified organisms, hereinafter 'GMOs', or food and feed products produced from GMOs, but does not require operators to sample and test products at each stage of the placing of the market for presence of GMOs or material produced from GMOs.

(2) According to Article 9(1) of Regulation (EC) No 1830/2003, Member States are, however, required to ensure that inspections and other control measures including sample checks and testing (qualitative and quantitative), as appropriate, are carried out to ensure compliance with that Regulation.

(3) In order to facilitate a coordinated approach for those inspections and control measures, Article 9(2) of Regulation (EC) No 1830/2003 requires that technical guidance on sampling and testing for GMOs and food and feed material produced from GMOs in products should be established.

(4) This guidance should cover products that have received authorisations for their placing on the market but is without prejudice to Article 4(5) of Directive 2001/18/EC of the European Parliament and of the Council [2] with regard to GMOs which are not authorised in the European Union.

[1] OJ L 268, 18.10.2003, p. 24.
[2] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003.

(5) The sampling and detection should be carried out using sound scientific and statistical protocols in order to achieve an appropriate level of confidence for detection of GMOs or material produced from GMOs.

(6) In developing the guidance, the Committee set up by Article 30 of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC has been consulted, and account has been taken of the work of the national competent authorities, the Standing Committee on the Food Chain and Animal Health and the Community Reference Laboratory.

(7) Where lots of non-GM seed or other plant propagating material are required to comply with standards on adventitious or technically unavoidable presence of genetically modified seeds or other plant propagating material, a legally-binding protocol on sampling and testing for the presence of genetically modified seeds or other plant propagating material should be developed in the context of the specific legislation on seeds and other plant propagating material; whereby the elements provided in that protocol should also serve as a basis for sampling and testing of other GM crop species not covered by the abovementioned legislation, where appropriate,

HEREBY RECOMMENDS:

I. **GENERAL PRINCIPLES**

1. For the purpose of fulfilling the requirements set out in Article 9(1) of Regulation (EC) No 1830/2003, Member States should take account of:

   (a) the past record of operators with respect to compliance with relevant legislation;

   (b) the reliability of any controls that operators have already carried out;

   (c) situations where non-compliance is suspected;

   (d) using means proportionate to the desired specific objectives and particularly in the light of experience gained;

   (e) the degree of heterogeneity and the point in the supply chain at which testing is being undertaken.

2. Official controls should be carried out without prior warning, except in cases where prior notification of an operator is necessary.

3. Official controls should be carried out at any stage of the production, processing, and storage, distribution of products that contain or may contain GMOs or food and feed produced from GMOs, including at the point of import [1].

[1] In accordance with Article 9(3) of Regulation (EC) No 1830/2003 relevant information concerning GMOs which are not authorised in the EU should, where available, be placed on a central register.

4. Official controls should not differentiate between products intended for export outside the Community and products intended for placing on the market within the Community.

5. Operators whose products are subject to sampling and analysis should be entitled to appeal for a second opinion. Official bodies should collect a sufficient number of counter samples for enforcement and referee purposes in order to guarantee operators appeal right and have a second opinion, as required by national legislation.

6. Alternative sampling strategies to those recommended in this guidance may be applied.

7. Alternative testing strategies to those recommended in this guidance may be applied provided such methods are approved by the Community Reference Laboratory established under Regulation (EC) 1829/2003.

8. Without prejudice to specific requirements laid down in EU legislation concerning food, feed and other controls, and in particular Directive 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition, Directive 70/373/EEC on the introduction of Community methods of sampling and analysis for the official control of feeding stuffs, Directive 89/397/EEC on the official controls of foodstuffs and Directive 93/99/EEC on the subject of additional measures concerning the official control on foodstuffs, Member States should ensure that official controls are carried out, so as to achieve the objectives of Regulation (EC) No 1830/2003.

II. **DEFINITIONS**

(a) *Lot* is defined as a distinct and specified quantity of material.

The following definitions take account of the type of material forming a lot and are in line with ISTA, ISO standards 6644 and 13690 and FAO (International Standards for Phytosanitary Measures):

seed lot: a specified quantity of seed, physically identifiable and uniform, not exceeding the maximum lot size as defined in the seeds Directives and forming the total or a part of a consignment;

other plant propagating material lot: a number of units of a single commodity identifiable by its homogeneity of composition, origin etc., not exceeding the maximum lot size as defined in the legislation on other plant propagating material, and forming the total or a part of a consignment;

food and feed products lot: quantity of product dispatched or received at one time and covered by a particular contract or shipping document.

(b) *Increment sample*: small equal quantity of product taken from each individual sampling point in the lot through the full depth of the lot (static sampling), or taken from the product stream during a stated portion of time (flowing commodities sampling).

(c) *File increment sample*: an increment sample that is retained for a specific period of time for further analysis.

(d) *Bulk sample*: quantity of product obtained by combining and mixing the increments taken from a specific lot.

(e) *Laboratory sample*: quantity of product taken from the bulk sample intended for laboratory inspection and testing.

(f) *Analytical sample*: homogenised laboratory sample, consisting either of the whole laboratory sample or a representative portion thereof.

(g) *Counter sample*: a sample retained for a specific period of time for enforcement or referee purposes.

(h) *Percentage of GM DNA*: the percentage of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes.

III. PRINCIPLES FOR SAMPLING PROTOCOLS

1. Member States should take account of the guidance on sampling protocols for products consisting of, containing or produced from GMOs when inspecting and controlling whether operators are complying with Articles 4 and 5 of Regulation (EC) No 1830/2003.

2. The Community Reference Laboratory established under Regulation (EC) No 1829/2003, and the nationally designated laboratories to the European Network of GMO Laboratories, hereinafter 'ENGL', will provide further guidance and assistance on the methods of sampling falling within the scope of this Recommendation.

3. Harmonised sampling procedures should be utilised for the purpose of estimating the presence of GMOs. These procedures should apply to seed and other plant propagating material, food, feed and agricultural commodity lots.

4. The following sampling procedures are defined in order to ensure that the samples collected and analysed are representative of the different types of commodities under investigation. Whereas sampling protocols for the presence of GM seeds and other plant propagating material in seed lots should be developed according to the specific legislation on seeds or other propagating material, sampling strategies for bulk commodities and food and feed products are addressed in separate sections that take into account commodity-specific properties.

IV. SAMPLING PROTOCOLS

1. Sampling seed and other plant propagating material lots

This section deals with the detection of genetically modified seeds or other plant propagating material in lots of seed or other plant propagating material of non-GM varieties or clones and the detection of GM seeds or other plant propagating material arising from a transformation event other than that designated for a lot of seed or other plant propagating material of a GM variety or clone.

Samples should be drawn in accordance with current international methods and where appropriate from lot sizes as defined in Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 92/34/EEC, 98/56/EEC, 1999/105/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC and 2002/57/EC. The general principles and methods of sampling of seeds and other plant propagating material should be in accordance with the International Seed Testing Association (ISTA) rules and the associated ISTA Handbook on Seed Sampling.

The sampling and testing schemes to be used for seeds or other plant propagating material should meet the requirements indicated in the specific legislation on seeds and other propagating material as regards statistical risks. Seed or other plant propagating material lot quality level and its associated statistical uncertainty are defined in relation to thresholds for GMOs and relate to the percentage of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes.

2. **Sampling bulk agricultural commodities**

The sampling protocol is based on a two-step procedure that allows, if necessary, to obtain estimates of GMO presence levels, together with their associated uncertainty expressed as Standard Deviation (SD), without imposing any assumption on the possible heterogeneity of the GMOs.

In order to allow the estimation of SD, in the first instance, a bulk sample should be produced and the derived analytical sample analysed for the presence of GM materials. Where the obtained analytical result is close to the established threshold (± 50 % of its value), the analysis of the individual file increment samples is recommended to provide a measure of the associated uncertainty.

The following documents should be taken into account:

(a) ISO standard 6644 (2002);

(b) ISO standard 13690 (1999);

(c) ISO standard 5725 (1994);

(d) ISO standard 2859 (1985);

(e) ISO standard 542 (1990).

2.1. *Protocol for sampling lots of bulk agricultural commodities*

It is recommended that sampling of bulk commodities (grains, oilseeds) takes place in accordance with the general principles and methods of sampling described in ISO standards 6644 and 13690. In case of flowing commodities, the sampling period should be defined, according to ISO standard 6644, as: total off-loading time/total number of increments. In case of static sampling, increments should be collected at specific sampling points. Such sampling points should be uniformly distributed throughout the lot volume, according to the principles described in ISO 13690. The number of increments or sampling points (where the increment samples for creating the bulk sample and the file increment samples are taken) is defined according to lot size, as follows:

Lot size in tonnes	Size of the bulk sample in kg	Number of incremental samples
≤ 50	5	10
100	10	20
250	25	50
≥ 500	50	100

In case of lots from 50 to 500 tonnes, the size of the bulk sample should be 0,01 % of the total lot size. In case of lots smaller than 50 tonnes, the size of the bulk sample should be 5 kg. In case of lots larger than 500 tonnes, the size of the bulk sample should be 50 kg. At each sampling interval (systematic sampling) or sampling point (static sampling) an increment of 1kg should be collected and split into two portions of 0,5 kg: one to be used as an increment for the production of the bulk sample, the other to be stored as a file increment sample.

Sampling of materials larger than grains (e.g. fruits, rhizomes, potatoes) should be carried out according to ISO standard 2859. Sampling of oilseed should be carried out according to ISO standard 542.

2.2. *Protocol for the preparation of the analytical samples*

A multiple-step protocol is recommended in order to minimise costs and maximise statistical power according to pre-defined acceptance levels.

Initially, the increment samples collected according to sub-section 2.1 are combined and mixed thoroughly, according to the procedures described in ISO standards 13690 and 6644, to form a bulk sample.

The bulk sample is used to create an analytical sample, according to the procedures described in ISO standards 13690 and 6644, and analysed for the presence of GMOs according to 'analytical test protocols/testing methods', as outlined in section V. If the result of the analysis is close to the established threshold (threshold ± 50 % of its value), an estimation of the associated uncertainty may be necessary (a protocol for estimating this uncertainty is foreseen in Article 2.3).

2.3. *Protocol for estimating uncertainty*

If there are 20 or fewer file increment samples, as in the case of smaller lots, all samples should be analysed individually and a decision as to labelling should be taken.

If there are more than 20 file increment samples, 20 samples should be randomly selected and individually analysed for the presence of GMOs. Analytical results from these 20 samples are used to estimate the GMO content of the lot and its associated uncertainty expressed as standard deviation (SD). If this uncertainty associated to the analysis of the 20 samples is acceptable, no additional analysis of the remaining file increment samples is necessary. If, instead, the level of associated uncertainty is not acceptable, additional analysis of the remaining file increment samples should be carried out.

The number of additional samples to be analysed should be established on a case-by-case basis, depending upon the level of uncertainty estimated from the initial 20 samples.

The sequential analytical process should stop when either or both of the following is the case:

— the estimated lot GMO content (mean GMO content of the analysed file increment samples) is above or below the established threshold ± 50 % of its value,

— the uncertainty associated to the measured lot GMO content reaches an acceptable level (± 50 % of the mean analytical result).

Where all samples have been tested a decision as to labelling should be taken.

2.4. *Protocol for sampling lots of food and feed products*

Sampling of pre-packaged food and feed products should be carried out according to the procedures described in ISO 2859.

Sampling of non pre-packaged food and feed products should be carried out according to the protocol described in sub-section 2.1.

V. ANALYTICAL TEST PROTOCOLS/TESTING METHODS

1. The Community Reference Laboratory established under Regulation (EC) No 1829/2003, and the nationally designated laboratories to the ENGL, will provide further guidance and assistance on the methods of testing falling within the scope of this Recommendation.

2. **Laboratory requirements**

Member States' laboratories carrying out the analyses in accordance with this Recommendation should be accredited according to EN ISO/IEC 17025/1999 or certified according to an appropriate scheme, and should regularly participate in proficiency testing schemes organised or co-ordinated by nationally or internationally recognised laboratories and/or by national, international organisations.

Foodstuffs submitted for analysis in accordance with this Recommendation should be submitted to laboratories complying with the provisions of Article 3 of Directive 93/99/EEC.

The analytical investigation of the samples should be carried out in accordance with the general laboratory and procedural requirements from the draft European standard prEN ISO 24276:2002.

3. **Analytical sample preparation**

When taking samples, the aim is to obtain a representative and homogeneous laboratory sample without introducing secondary contamination. Member States should use the draft European standard prEN ISO 24276:2002 and prEN ISO 21571:2002 that indicate strategies for the homogenisation of the laboratory sample, the reduction of the laboratory sample to the test sample, the preparation of the test sample and the extraction of target analyte.

Obtaining samples of seeds should be done according to the ISTA International Rules for Seed Testing. Obtaining plant-propagating material samples should be done according to current international methods, in so far such methods exist.

4. **Analytical testing**

The current scientific knowledge does not allow for the detection and quantification of all GMOs or food and feed material produced from GMOs that have been approved for the placing on the market by using a single method.

Several testing approaches are likely to provide equally reliable results. These may include one or a combination of the following:

(a) qualitative methods, that may be event-specific, construct-specific or genetic element-specific;

(b) quantitative methods, that may be event-specific, construct-specific or genetic element-specific.

It may be appropriate to start with a screening method to test whether GMOs are present or not. If a positive result is obtained, specific methods for a genetic construct and/or transformation event should be carried out. If different GMOs containing the same genetic construct are present on the market, an event specific method is strongly recommended. The results of quantitative analysis should be expressed as the percentage of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes. Whenever possible, laboratories should use a method validated according to internationally recognised criteria (e.g. ISO 5725/1994 or IUPAC harmonised protocol), and include the use of certified reference material.

An up-dated list of validated methods, including validated methods reported to *Codex Alimentarius*, is available in (http://biotech.jrc.it).

5. **Absence of validated methods**

If a situation arises where no validated method exists, for instance to test whether GMOs are present or not, Member States' laboratories should carry out an in-house validation of the method according to internationally recognised criteria. If no validated method is available for the matrix under analysis, it is recommended to select from the database available on http://biotech.jrc.it a method that has been validated on a similar matrix or raw material. Before adoption, the performance of such method should be tested on the matrix of interest.

6. **Expression and interpretation of the results of the analyses**

In case of qualitative methods, the limit of detection (LOD) is the lowest level of analyte that can be reliably detected, given a known number of target taxon genome copies.

In case of quantitative methods, the limit of quantification (LOQ) is the lowest level of analyte that can be reliable quantified, given a known number of target taxon genome copies. Results of quantitative analysis should be expressed as GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes. If the GM target sequence content is below the limit of quantification (LOQ), the results shall only be expressed qualitatively.

It is recommended to interpret the results according to the instructions given in the draft European standard prEN ISO 24276:2002.

VI. **FINAL PROVISIONS**

Sampling and detection methodology, including relevant protocols and documents, should continue to be developed and up-graded taking account of any change in thresholds and threshold values established under Articles 12, 24 and 47 of Regulation (EC) No 1829/2003, Article 21(2) and (3) of Directive 2001/18/EC and under other Community legislation, the report under Article 12 of Regulation (EC) No 1830/2003 concerning the implementation of that regulation, advances in technology and developments in international fora.

Done at Brussels, 4 October 2004.

For the Commission

Margot WALLSTRÖM

Member of the Commission

ANNEX 9

COMMISSION REGULATION (EC) No 1981/2006

of 22 December 2006

on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [1], and in particular Article 32, fifth sub-paragraph, thereof,

Whereas:

(1) Regulation (EC) No 1829/2003 provides for a Community reference laboratory (CRL) to carry out certain duties and tasks set out in that Regulation. It also provides that the CRL is to be assisted by national reference laboratories.

(2) Methods of detection and identification which have to be tested and validated by the CRL and samples and control samples have to meet the requirements laid down in Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation [2].

(3) It is necessary to provide detailed rules for implementing Article 32 of Regulation (EC) No 1829/2003.

(4) The financial contribution to be paid by applicants in accordance with Article 32 of Regulation (EC) No 1829/2003 should be used only towards supporting the costs of the duties and tasks as set out in the Annex to that Regulation. The CRL should be authorised to charge a financial contribution to applicants for new authorisations, for renewal of authorisations and in the case of modification of authorisations where appropriate.

(5) The determination of the amount of the financial contribution should take into account the burden of work to be carried out by the CRL in each case, depending on the level of method testing and validation already carried out prior to the submission of the application for authorisation.

(6) Applicants should be encouraged to provide data that refer to modules which have already been validated and published by the CRL in order to facilitate both the establishment of the application dossier and the validation of the detection method.

(7) A financial contribution should be levied on a flat-rate basis in order to contribute to supporting the costs incurred in the comprehensive data analysis and in-house laboratory verification of the method and samples received to be carried out by the CRL in all cases where a new method is submitted.

(8) An additional financial contribution should be charged to applicants where the validation of the proposed method requires the performance of a collaborative study involving national reference laboratories in order to comply with the criteria referred to in Annex I of Regulation (EC) No 641/2004.

(9) The amount of the financial contributions should cover the costs directly associated with the validation tasks to be performed. Those include in particular the manpower, the reagents and other associated disposable material, the distribution of material to members of the European Network of GMO laboratories (ENGL) where appropriate and the administrative costs. They should be calculated on the basis of the experience gained by the Commission's Joint Research Centre in carrying out validations of detection methods, including collaboration with members of the ENGL where appropriate, and should not exceed the actual costs incurred in carrying out that validation.

[1] OJ L 268, 18.10.2003, p. 1.
[2] OJ L 102, 7.4.2004, p. 14.

(10) Where the validation costs for a specific application for authorisation exceeds substantially the amount of the financial contributions provided for in this Regulation, the CRL should be able to charge an additional contribution to the applicant. In that case, the applicant should have the right to be exempted from the payment of the additional contribution if he withdraws its application within a set time limit.

(11) Due consideration should be given to the specific case of biotechnological research originating in developing countries. A reduction of the amount of the financial contribution should therefore be provided where the head office of the applicant for authorisation is established in a developing country.

(12) In order to facilitate the participation of small and medium-sized enterprises (SMEs) to the Community procedure for authorisation of genetically modified (GM) food and feed, it is appropriate to provide for a reduced financial contribution where applicants are SMEs. The model declaration on the information relating to the qualification of an enterprise as an SME [1] could serve for the written evidence to be provided by applicants as to their SME status.

(13) Regulation (EC) No 1829/2003 already lays down the rule that applicants should make a financial contribution, so any applicants who have lodged applications before the entry into force of this Regulation will be aware of this rule. Consequently, the financial contribution should also be required for applications for authorisation submitted before the date of entry into force of this Regulation.

(14) National reference laboratories assisting the CRL for the duties and tasks set out in the Annex to Regulation (EC) No 1829/2003 should be part of the European Network of GMO Laboratories (ENGL), whose members represent the state-of-the-art in GMO detection, including expertise in method development, performance and validation, sampling and management of biological and analytical uncertainties. They should also meet specific requirements where they have to assist the CRL specifically for testing and validation of detection methods in the context of collaborative studies according to international standards.

(15) In the interests of stability and efficacy and in order to make the validation procedure operational in accordance with this Regulation, it is necessary to designate the national reference laboratories apt to assist the CRL for testing and validation of detection methods.

(16) The relationship between the national reference laboratories assisting the CRL for testing and validation of detection methods and between them and the CRL should be defined by a written agreement.

(17) The Annex to Regulation (EC) No 1829/2003 should be amended accordingly.

(18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation lays down detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 as regards:

(a) the contribution to the costs of the tasks of the Community reference laboratory (CRL) and of the national reference laboratories, as referred to in the Annex to the said Regulation; and

(b) the establishment of national reference laboratories.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(a) 'full validation procedure' means the assessment through a ring trial involving national reference laboratories of the method performance criteria set by the applicant as compliant with the document entitled 'Definition of minimum performance requirements for analytical methods of GMO testing' referred to in point 1(B) of Annex I to Regulation (EC) No 641/2004, and the assessment of the repeatability and trueness of the method provided by the applicant;

(b) 'small and medium-sized enterprise (SME)' means small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC [2];

[1] Commission communication 2003/C 118/03 (OJ C 118, 20.5.2003, p. 5). Corrigendum published in OJ C 156, 4.7.2003, p. 14.

[2] OJ L 124, 20.5.2003, p. 36.

(c) 'developing countries' means beneficiary countries as referred to in Article 2 of Council Regulation (EC) No 980/2005 of 27 June 2005 applying a scheme of generalised tariff preferences [1];

(d) 'application' where used without further specification, means an application for authorisation submitted in accordance with Article 5 or 17 of Regulation (EC) No 1829/2003, including applications submitted under other Community legislation which are transformed or supplemented in accordance with Article 46 of that Regulation. It also refers to applications for renewal of authorisations according to Article 11 or 23 of Regulation (EC) No 1829/2003 and modifications of authorisations according to Articles 9(2), 10, 21(2) or 22 of that Regulation, where the CRL is requested to test and validate a method of detection and identification.

Article 3

Contributions

1. For each application, a flat-rate contribution of EUR 30 000 shall be paid by the applicant to the CRL.

2. Where a full validation procedure of a method of detection and identification for a single GMO event according to the requirements laid down in Annex I of Regulation (EC) No 641/2004 is required, the CRL shall request the applicant to pay an additional contribution of EUR 60 000.

This amount shall be multiplied by the number of GMO events to be fully validated.

The CRL shall reduce the amount of the additional contribution, in proportion of the costs saved:

(a) where the material needed to perform the full validation procedure is supplied by the applicant; and/or

(b) where the applicant provides data that refer to modules, such as DNA extraction protocols and species specific reference systems, already validated and published by the CRL.

3. Where the costs of the validation of the detection method proposed by the applicant exceed substantially the amount of the financial contributions mentioned under paragraphs 1 and 2, an additional contribution shall be requested.

The additional contribution shall cover 50 % of the part of the costs exceeding the amount of the contributions referred to in paragraphs 1 and 2.

4. The contributions provided for in paragraphs 1 and 2 remain due in case of withdrawal of the application.

Article 4

Reductions and exemptions

1. Where the applicant is a SME or has its head office established in a developing country, the financial contributions referred to in Article 3(1) and (2) shall be reduced by 50 %.

2. Where the same method of detection and identification has already been included in a previous application by the same applicant for products related to the same GMO and that method has been validated and published by the CRL or its validation is pending, that applicant shall be exempted from the payment of the financial contributions referred to Article 3.

However, where costs are incurred by the CRL in carrying out the validation tasks laid down in Regulation (EC) No 1829/2003, the CRL may charge the applicant a maximum contribution of EUR 30 000.

3. Article 3(3) shall not apply where the applicant is a SME or has its head office established in a developing country, nor to applications submitted before the entry into force of this Regulation.

Article 5

Procedure

1. The applicant shall provide evidence that the flat-rate contribution of EUR 30 000 referred to in Article 3(1) has been paid to the CRL when it submits the samples of the food and feed and their control samples to the CRL in accordance with Article 5(3)(j) or Article 17(3)(j) of Regulation (EC) No 1829/2003.

2. Where, as provided for in Article 3(2), a full validation procedure is required, the CRL shall notify the applicant in writing of this fact and require the payment of the amount due in accordance with that provision.

3. Where, as provided for in Article 3(3), the CRL expects the costs of the validation of the detection method proposed by the applicant to exceed substantially the amount of the financial contributions referred to in Article 3(1) and (2), it shall notify the applicant in writing of the estimated amount of the additional costs.

[1] OJ L 169, 30.6.2005, p. 1.

If, within one month of the date of receipt of the notification, the applicant withdraws its application, the additional contribution referred to in Article 3(3) is not due.

After completion of the validation of the detection method, the CRL shall notify the applicant in writing the actual and duly justified costs incurred in carrying out the validation of the detection method and require payment of the contribution due in accordance with Article 3(3).

4. Where, as provided for in Article 4(2), costs are incurred, the CRL shall notify the applicant in writing of the amount of the contribution due, including a justification of that amount.

5. Where an application has been submitted before the date of entry into force of this Regulation, the CRL shall, within three months of that date, notify in writing the applicant of the amount of the financial contribution to be paid according to Article 3(1) and (2) as appropriate.

6. When a reduction of the contribution is claimed in accordance with Article 4(1), the application shall be accompanied by written evidence that the conditions laid down in that Article are fulfilled. The CRL may require supplementary information where appropriate.

7. The contributions mentioned in paragraph 2 to 5 shall be payable by the applicant within 45 days of the date of reception of the notification.

Where the applicant has not provided proof of payment within the set time limit, and where the evaluation report referred to in point 3(e), of the Annex to Regulation (EC) No 1829/2003 has not yet been sent to the European Food Safety Authority (the Authority), the CRL shall not submit it to the Authority until the reception of the due payment. The CRL shall immediately notify the Authority that its report will be delayed, to enable the Authority to inform the applicant and take any further steps required under Articles 6(1) to (2) and 18(1) to (2) of Regulation (EC) No 1829/2003.

Article 6

National reference laboratories assisting the CRL for testing and validating the methods of detection and identification

1. Laboratories which assist the CRL in testing and validating the method of detection and identification, as provided for in Articles 6(3)(d) and 18(3)(d) of Regulation (EC) No 1829/2003, shall fulfil the minimum requirements laid down in Annex I to this Regulation.

The laboratories listed in Annex II, are meeting those requirements, and are hereby appointed as national reference laboratories under Regulation (EC) No 1829/2003 to assist the CRL for testing and validating the method of detection.

2. The CRL and the national reference laboratories listed in Annex II shall enter into a written agreement to define the relations between them, notably in financial matters. In particular, the written agreement shall provide that the CRL is to distribute a share of the financial contributions it receives to the national reference laboratories.

Article 7

Reporting

The CRL shall be responsible for preparing an annual report on each year's activities carried out for the implementation of this Regulation and shall submit it to the Commission. The national reference laboratories under Regulation (EC) No 1829/2003 shall contribute to this annual report.

The CRL may also organise an annual meeting with the national reference laboratories, in view of the establishment of the annual report.

Article 8

Amendment to Regulation (EC) No 1829/2003

The Annex to Regulation (EC) No 1829/2003 is amended in accordance with Annex III to this Regulation.

Article 9

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 December 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

Requirements for laboratories assisting the Community reference laboratory for testing and validation of methods for detection, as referred to in Article 6(1)

Laboratories assisting the Community reference laboratory for testing and validating the method for detection, as set out in point 3(d) of the Annex to Regulation (EC) No 1829/2003, must:

(a) be accredited, or being in the process of accreditation according to EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' or an equivalent international standard which ensures that the laboratories:

— have suitably qualified staff with adequate training in analytical methods used for the detection and identification of GMOs and GM food and feed,

— possess the equipment needed to carry out the analysis of GMOs and GM food and feed,

— have an adequate administrative infrastructure,

— have sufficient data-processing capacity to produce technical reports and to enable rapid communication with the other laboratories participating in the testing and validation of detection methods;

(b) provide assurance that their staff respect the confidential nature of subjects, data, results or communications involved in the handling of applications for authorisation, for renewal of authorisations or for modification of authorisations submitted in accordance with Regulation (EC) No 1829/2003 and in particular the confidential information referred to in Article 30 of that Regulation.

ANNEX II

National reference laboratories assisting the CRL for testing and validation of methods for detection, as referred to in Article 6(1)

Belgique/België

— Centre wallon de Recherches agronomiques (CRA-W),

— Institut Scientifique de Santé Publique (ISP) — Wetenschappelijk Instituut Volksgezondheid (WIV),

— Instituut voor Landbouw- en Visserijonderzoek (ILVO);

Česká republika

— Státní veterinární ústav Jihlava (SVU Jihlava),

— Státní zdravotní ústav (SZÚ), Laboratoř pro molekulárně biologické metody (LMBM), Centrum hygieny potravinových řetězců v Brně,

— Státní zemědělská a potravinářská inspekce (SZPI),

— Vysoká škola chemicko-technologická v Praze (VŠCHT),

— Výzkumný ústav rostlinné výroby (VÚRV), Praha;

Danmark

— Danmarks Fødevareforskning (DFVF),

— Ministeriet for Fødevarer, Landbrug og Fiskeri, Plantedirektoratet, Laboratorium for Diagnostik i Planter, Frø og Foder;

Deutschland

— Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit (LGL),

— Berliner Betrieb für Zentrale Gesundheitliche Aufgaben (BBGes) — Institut für Lebensmittel, Arzneimittel und Tierseuchen (ILAT),

— Bundesinstitut für Risikobewertung,

— Chemisches und Veterinäruntersuchungsamt (CVUA) Freiburg,

— Chemisches und Veterinäruntersuchungsamt Ostwestfalen-Lippe,

— Institut für Hygiene und Umwelt der Hansestadt Hamburg,

— Landesamt für Landwirtschaft, Lebensmittelsicherheit und Fischerei — Mecklenburg-Vorpommern (LALLF MV),

— Landesamt für Soziales, Gesundheits- und Verbraucherschutz — Abteilung F: Verbraucherschutz, Veterinärmedizin, Lebensmittelhygiene und Molekularbiologie,

— Landesamt für Umweltschutz Sachsen-Anhalt,

— Landesamt für Verbraucherschutz Sachsen-Anhalt — Fachbereich Lebensmittelsicherheit,

— Landesbetrieb Hessisches Landeslabor — Standort Kassel,

— Landeslabor Brandenburg,

— Landeslabor Schleswig-Holstein,

— Landesuntersuchungsamt Rheinland-Pfalz — Institut für Lebensmittelchemie Trier,

— Landesuntersuchungsanstalt für das Gesundheits- und Veterinärwesen Sachsen (LUA),

— Landwirtschaftliche Untersuchungs- und Forschungsanstalt Rostock der LMS Mecklenburg-Vorpommern,

— Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit (LAVES) — Lebensmittelinstitut (LI) Braunschweig,

— Sächsische Landesanstalt für Landwirtschaft — Fachbereich Landwirtschaftliches Untersuchungswesen,

— Staatliche Landwirtschaftliche Untersuchungs- und Forschungsanstalt Augustenberg (Baden-Württemberg),

— Thüringer Landesamt für Lebensmittelsicherheit und Verbraucherschutz (TLLV);

Eesti

— DNA analüüsi laboratoorium, Geenitehnoloogia Instituut (GTI), Tallinna Tehnikaülikool (TTÜ),

— Keemilise ja Bioloogilise Füüsika Instituut (KBFI), Molekulaargeneetika laboratoorium (MG),

— Veterinaar-ja Toidulaboratoorium (VTL);

Elláda

— Εθνικό Ίδρυμα Αγροτικής Έρευνας Εργαστήριο Γενετικής Ταυτοποίησης Γεωργικών Προϊόντων, Μικροοργανισμών και Ελέγχου Σπόρων Σποράς για την Ανίχνευση, Γενετικών Τροποποιήσεων,

— Υπουργείο Οικονομίας και Οικονομικών, Γενική Διεύθυνση Γενικού Χημείου του Κράτους (ΓΧΚ), Διεύθυνση Τροφίμων — Αθήνα;

España

— Centro Nacional de Alimentación, Agencia Española de Seguridad Alimentartia (CNA-AESA),

— Laboratorio Arbitral Agroalimentario del Ministerio de Agricultura, Pesca y Alimentación (LAA-MAPA);

France

— Groupement d'Intérêt Public — Groupe d'Etude et de contrôle des Variétés et des Semences (GIP-GEVES),

— Laboratoire de Phytopathologie et de méthodologies de la détection (INRA Versailles),

— Laboratoire Direction Générale de la Consommation, de la Concurrence et de la Répression des Fraudes de Strasbourg (Laboratoire de la DGCCRF de Strasbourg),

— Laboratoire National de la Protection des Végétaux d'Orléans (LNPV Orléans);

Ireland

— The State Laboratory (SL), Celbridge;

Italia

— Ente Nazionale Sementi Elette (E.N.S.E.), Laboratorio Analisi Sementi,

— Istituto Superiore di Sanità, Centro Nazionale per la Qualità degli Alimenti e per i Rischi Alimentari (CNQARA),

— Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana, Centro di Referenza Nazionale per la Ricerca di OGM (CROGM);

Kypros

— Γενικό χημείο του κράτους (γχκ);

Latvija

— Pārtikas un veterinārā dienesta Nacionālais diagnostikas centrs (PVD NDC);

Lietuva

— Nacionalinė Veterinarijos Laboratorija, GMO Tyrimų Skyrius;

Luxembourg

— Laboratoire National de Santé (LNS), Division du contrôle des denrées alimentaires;

Magyarország

— Országos Élelmiszerbiztonsági és Táplálkozástudományi Intézet (OÉTI),

— Országos Mezőgazdasági Minősítő Intézet, Központi Laboratórium (OMMI);

Nederland

— RIKILT Instituut voor Voedselveiligheid,

— Voedsel en Waren Autoriteit (VWA);

Österreich

— Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH — Kompetenzzentrum Biochemie (AGES - CC BIOC),

— Umweltbundesamt GmbH;

Polska

— Instytut Biochemii i Biofizyki Polskiej Akademii Nauk, Laboratorium Analiz Modyfikacji Genetycznych Instytutu Biochemii i Biofizyki Polskiej Akademii Nauk (GMOIBB), Warszawa,

— Instytut Hodowli i Aklimatyzacji Roślin (IHAR); Laboratorium Kontroli Genetycznie Modyfikowanych Organizmów, Błonie,

— Instytut Zootechniki (National Feed Laboratory – NFL), Lublin,

— Państwowego Instytutu Weterynaryjnego – Państwowego Instytutu Badawczego w Puławach, Puławy,

— Regionalne Laboratorium Badań Żywności Genetycznie Modyfikowanej (RLG);

Portugal

— Direcção-Geral de Protecção das Culturas (DGPC), Laboratório de Caracterização de Materiais de Multiplicação de Plantas (LCMMP),

— Instituto Nacional de Engenharia Tecnologia e Inovação (INETI), Laboratório para a Indústria Alimentar (LIA);

Slovenija

— Kmetijski inštitut Slovenije (KIS), Ljubljana,

— Nacionalni inštitut za biologijo (National institute of Biology, NIB), Ljubljana;

Slovensko

— Štátny veterinárny a potravinový ústav, Dolný Kubín (State Veterinary and Food Institute Dolný Kubín),

— Ústav molekulárnej biológie SAV (Molecular Biology Institute of the Slovak Academy of Slovakia),

— Ústredný kontrolný a skúšobný ústav poľnohospodársky, Oddelenie molekulárnej biológie Bratislava, (Central Control and Testing Institute of Agriculture);

Suomi/Finland

— Tullilaboratorio

Sverige

— Livsmedelsverket (SLV)

United Kingdom

— Central Science Laboratory (CSL),

— LGC Limited (LGC),

— Scottish Agricultural Science Agency (SASA).

ANNEX III

Amendments to the Annex to Regulation (EC) No 1829/2003

Points 2, 3 and 4 are replaced by the following:

'2. For the duties and tasks outlined in this Annex, the Community reference laboratory shall be assisted by the national reference laboratories referred to in Article 32, which shall consequently be considered as members of the consortium referred to as the "European Network of GMO laboratories".

3. The Community reference laboratory shall be responsible, in particular, for:

(a) the reception, preparation, storage, maintenance and distribution to the members of the European Network of GMO laboratories of the appropriate positive and negative control samples, subject to assurance given by such members of the respect of the confidential nature of the data received where applicable;

(b) without prejudice to the responsibilities of the Community reference laboratories laid down in Article 32 of Regulation (EC) No 882/2004 of the European Parliament and of the Council (*), the distribution to national reference laboratories within the meaning of Article 33 of that Regulation of the appropriate positive and negative control samples, subject to assurance given by such laboratories of the respect of the confidential nature of the data received where applicable;

(c) evaluating the data provided by the applicant for authorisation for placing the food or feed on the market, for the purpose of testing and validation of the method for sampling and detection;

(d) testing and validating the method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed;

(e) submitting full evaluation reports to the Authority.

4. The Community reference laboratory shall play a role in dispute settlements concerning the results of the tasks outlined in this Annex, without prejudice to the responsibilities of the Community reference laboratories laid down in Article 32 of Regulation (EC) No 882/2004.

(*) OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1.'

ANNEX 10

COMMISSION REGULATION (EU) No 619/2011

of 24 June 2011

laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [1], and in particular Article 11(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed [2] does not provide for special rules for the control of material which contains, consists of or is produced from GMOs (GM material) for which an EU authorisation procedure is pending or GM material the authorisation of which has expired. Experience has shown that in the absence of such rules, the official laboratories and the competent authorities apply different methods of sampling and different rules for the interpretation of the results of the analytical tests. This may lead to different conclusions as regards the compliance of a product with Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [3]. As a result of the lack of harmonised rules, economic operators are faced with legal uncertainty and there is a risk that the functioning of the internal market will be affected.

(2) Different international information exchange mechanisms providing information on the safety assessments performed by countries authorising the commercialisation of GMOs are in place. In accordance with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity of which all Member States are Parties, Parties to the Protocol have to inform the other Parties through the Biosafety Clearing House (BCH) on any final decision regarding domestic use, including placing on the market, of a GMO that may be subject to transboundary movement for direct use as food or feed or for processing. This information shall contain, inter alia, a risk assessment report. Countries which are not Parties to the Protocol may also provide such information on a voluntary basis. International information exchange mechanisms regarding the authorisation of GMOs and their safety assessments are also provided by FAO and OECD.

(3) The EU imports significant quantities of commodities produced in third countries where GMO cultivation is widespread. While these imported commodities are used both in the production of food and feed, the majority of the commodities likely to contain GMOs are destined for the feed sector thereby entailing a higher risk of trade disruption for that sector in cases where Member States apply different rules for official controls. It appears therefore appropriate to limit the scope of this Regulation to the feed sector which, in comparison with other sectors related to the production of foodstuffs, has a higher likelihood for GM presence.

(4) Regulation (EC) No 1829/2003 provides that the placing on the market of genetically modified feed is subject to an authorisation procedure. The authorisation procedure includes the publication of an EFSA opinion of which the main component is a safety assessment. In giving its opinion, EFSA consults Member States upon receipt of a valid application and Member States have 3 months to make their opinions known. The opinion of EFSA has also to include a method for detection validated by the European Union Reference Laboratory (EU-RL).

(5) In practice, the validation by the European Union Reference Laboratory (EU-RL) is carried out independently of the other elements provided for in the authorisation procedure. Generally the method is validated and published before all of the other elements are fulfilled for completing the EFSA opinion. These methods are published on the website of the EU-RL and are available to the competent authorities as well as to any interested parties.

[1] OJ L 165, 30.4.2004, p. 1.
[2] OJ L 54, 26.2.2009, p. 1.
[3] OJ L 268, 18.10.2003, p. 1.

(6) A method may only be validated if it complies with the detailed rules for the fitness of the method set out in Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation [1]. In addition, as required by that Regulation, common criteria for minimum performance requirements for analytical methods for GMO testing have been set [2].

(7) The methods of analysis validated by the EU-RL in the context of the authorisation procedure and for the placing on the market, use and processing of existing products within the meaning of Article 20 of Regulation (EC) No 1829/2003 are event-specific quantitative methods. They are validated through a collaborative trial in accordance with the principles of ISO 5725 International standard and/or the International Union of Pure and Applied Chemistry (IUPAC) protocol. As a matter of fact, the EU-RL is currently the sole laboratory in the world validating quantitative event-specific methods in accordance with the above mentioned standards in the context of pre-marketing authorisation procedures. These quantitative methods are considered to be more appropriate than qualitative methods for the purpose of ensuring the harmonisation of the official controls. Indeed testing procedures using qualitative methods require other sampling schemes as they are otherwise associated with higher risks to provide diverging results regarding the presence or absence of genetically modified material. It is therefore appropriate to use the methods of analysis validated by the EU-RL in the context of the authorisation procedure to prevent diverging analytical results amongst Member States.

(8) Certified reference material should also be available to enable control laboratories to perform their analysis.

(9) Accordingly, the scope of this Regulation should cover the detection in feed of GM material authorised for commercialisation in a third country and for which an authorisation procedure is pending for more than 3 months under Regulation (EC) No 1829/2003 where the event-specific quantitative methods of analysis submitted by the applicant have been validated by the EU-RL and provided that the certified reference material is available.

(10) The scope of this Regulation should also cover GM material the authorisation of which has expired. It should therefore apply to feed containing, consisting of or produced from SYN-EV176-9 and MON-ØØØ21-9xMON-ØØ81Ø-6 maize and ACS-BNØØ4-7xACS-BNØØ1-4, ACS-BNØØ4-7xACS-BNØØ2-5 and ACS-BNØØ7-1 oilseed rape for which a quantitative method has been validated by the European Union Reference Laboratory provided that the certified reference material is available. These GM materials were placed on the market before the application of Regulation (EC) No 1829/2003 and were notified as existing products under Article 20 of that Regulation. As the seeds were no more commercialised at global scale, the respective notifiers informed the Commission that they had no intention to submit an application for the renewal of the authorisation of the products concerned. As a consequence, the Commission adopted Decisions 2007/304/EC [3], 2007/305/EC [4], 2007/306/EC [5], 2007/307/EC [6] and 2007/308/EC [7] on the withdrawal from the market of the products concerned (obsolete products). These Decisions provide a tolerance for the presence in products of material which contain, consist of or are produced from SYN-EV176-9 and MON-ØØØ21-9xMON-ØØ81Ø-6 maize and ACS-BNØØ4-7xACS-BNØØ1-4, ACS-BNØØ4-7xACS-BNØØ2-5 and ACS-BNØØ7-1 oilseed rape provided that this presence is adventitious or technically unavoidable and in a proportion no higher than 0,9 % for a limited period which expires on 25 April 2012. It is appropriate to ensure that at the time of the expiry of the tolerance period set out in Decisions 2007/304/EC, 2007/305/EC, 2007/306/EC, 2007/307/EC and 2007/308/EC this Regulation applies also to the detection of these obsolete products in feed. It should also apply to any other GM material the authorisation of which is not renewed at the expiry of the authorisation due to the phasing out of the product.

(11) Harmonisation of the official controls of feed for the detection of GM material falling under the scope of this Regulation should also be ensured through the adoption of common methods of sampling.

(12) These methods should be based on recognised scientific and statistical protocols and, when available, on international standards and should cover the different steps of sampling, including the rules applicable to the sampling of the material, the precautions to be taken in the course of sampling and preparation of samples, the conditions to be applied for taking incremental samples and replicate laboratory samples, the handling of laboratory samples and the sealing and labelling of samples. To ensure adequate representativeness of the samples taken for official control purposes, specific conditions adapted to the fact that the lot of feed is presented in bulk agricultural commodities, pre-packaging or retail should also be adopted.

[1] OJ L 102, 7.4.2004, p. 14.
[2] http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requirements_Analytical_methods.pdf
[3] OJ L 117, 5.5.2007, p. 14.
[4] OJ L 117, 5.5.2007, p. 17.
[5] OJ L 117, 5.5.2007, p. 20.
[6] OJ L 117, 5.5.2007, p. 23.
[7] OJ L 117, 5.5.2007, p. 25.

(13) It is also appropriate to harmonise the rules for the interpretation of the results of the analysis, to ensure that throughout the European Union the same conclusion is drawn from the same analytical results. In this context, it is also necessary to take into account the technical constraints associated with any method of analysis, in particular at trace levels since analytical uncertainty increases with decreasing levels of GM material.

(14) To take these constraints into account, as well as the need to ensure that controls are both feasible, robust and proportionate, as set out in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1], it is appropriate to set as a Minimum Required Performance Limit (MRPL) the lowest level of GM material which is considered by the EU-RL for the validation of quantitative methods. This level corresponds to 0,1 % related to mass fraction of GM material in feed and is the lowest level where results are satisfactorily reproducible between official laboratories when appropriate sampling protocols and methods of analysis for measuring feed samples are applied.

(15) The methods validated by the EU-RL are specific to each transformation event irrespective of the fact that the transformation event is present in one or several GMOs containing one or several transformation events. The MRPL should thus apply to the whole GM material containing the measured transformation event.

(16) Measurement uncertainty should be determined by each official laboratory and confirmed as described in the guidance document on Measurement Uncertainty for GMO testing laboratories [2] developed by the Joint Research Centre of the Commission (JRC).

(17) A decision of non-compliance of the feed should therefore only be taken when GM material falling under the scope of this Regulation is present at levels equal or above the MRPL, measurement uncertainty being taken into account.

(18) The rules established by this Regulation should not affect the possibility for the Commission, or where applicable for a Member State, to adopt emergency measures in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002.

(19) These implementing rules should be adapted if this becomes necessary to take account of new developments in particular as regards their impact on the internal market and on food and feed operators.

(20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

1. For the purposes of this Regulation, the following definitions apply:

(1) 'Precision — Relative Repeatability Standard Deviation (RSDr)': The relative standard deviation of test results obtained under repeatability conditions. Repeatability conditions are conditions where test results are obtained with the same method, on identical test items, in the same laboratory, by the same operator, using the same equipment within short intervals of time;

(2) 'Minimum Required Performance Limit (MRPL)': the lowest amount or concentration of analyte in a sample that has to be reliably detected and confirmed by official laboratories;

(3) 'GM material': material which contains, consists of or is produced from GMOs.

2. The definitions set out in Article 2 of Regulation (EC) No 1829/2003 and in Annex I to Regulation (EC) No 152/2009 apply.

Article 2

Scope

This Regulation shall apply to the official control of feed with respect to the presence of the following material:

(a) GM material authorised for commercialisation in a third country and for which a valid application has been submitted under Article 17 of Regulation (EC) No 1829/2003 and for which the authorisation procedure has been pending for more than 3 months provided that:

(i) it has not been identified by EFSA as susceptible to have adverse effects on health or the environment when present under the MRPL;

[1] OJ L 31, 1.2.2002, p. 1.
[2] http://www.irmm.jrc.be/html/reference_materials_catalogue/user_support/EUR22756EN.pdf

(ii) the quantitative method requested under that Article has been validated and published by the European Union Reference Laboratory; and

(iii) that the certified reference material fulfils the conditions set out in Article 3;

(b) after 25 April 2012, GM material notified under Article 20 of Regulation (EC) No 1829/2003 of which the authorisation has expired and for which a quantitative method has been validated and published by the European Union Reference Laboratory provided that certified reference material fulfils the conditions set out in Article 3; and

(c) GM material for which the authorisation has expired due to the fact that no application for renewal in accordance with Article 23 of Regulation (EC) No 1829/2003 has been submitted provided that certified reference material fulfils the conditions set out in Article 3.

Article 3

Certified reference material

1. Certified reference material must be available to Member States and any third party.

2. Certified reference material shall be produced and certified in accordance with ISO guides 30 to 35.

3. The information accompanying the certified reference material shall include information on the breeding of the plant which has been used for the production of the certified reference material and on the zygosity of the insert(s). The certified value of the GMO content shall be given in mass fraction and, where available, in copy number per haploid genome equivalent.

Article 4

Methods of sampling

Samples for the official control of feed as regards the presence of the GM material referred to in Article 2, shall comply with the methods of sampling, as set out in Annex I.

Article 5

Sample preparation, methods of analysis and interpretation of results

The preparation of laboratory samples, the methods of analysis and the interpretation of results shall comply with the requirements set out in Annex II.

Article 6

Measures in case of detection of GM material referred to in Article 2

1. Where results of analytical tests indicate the presence of GM material referred to in Article 2 are at or above the MRPL as defined in accordance with the rules of interpretation set out in Annex II Part B, the feed shall be considered as non-compliant with Regulation (EC) No 1829/2003. Member States shall immediately notify this information through the RASFF in accordance with Article 50 of Regulation (EC) No 178/2002.

2. Where results of analytical tests indicate the presence of GM material referred to in Article 2 is below the MRPL as defined in accordance with the rules of interpretation set out in Annex II Part B, Member States shall record this information and notify the Commission and the other Member States by 30 June of each year. Recurrent findings over a period of time of 3 months shall be notified without delay.

3. The Commission shall or a Member State may, where appropriate, adopt emergency measures in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002.

Article 7

List of GM material referred to in Article 2

The Commission shall publish the list of GM material complying with the conditions set out in Article 2 on its website. The list shall include information as to the place where the certified reference material can be accessed as required by Article 17(3)(j) of Regulation (EC) No 1829/2003 and, if applicable, information on the measures adopted in accordance with paragraph 3 of Article 6 of this Regulation.

Article 8

Review

The Commission shall monitor the application of this Regulation and its impact on the internal market as well as on feed, livestock and other operators, and, if necessary, bring forward proposals to review this Regulation.

Article 9

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 June 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX I

METHODS OF SAMPLING

1. For the purpose of applying Annex I to Regulation (EC) No 152/2009, GM material shall be considered as a substance likely to be distributed non-uniformly throughout the feed.

2. By derogation from points 5.B.3., 5.B.4 and 6.4 of Annex I to Regulation (EC) No 152/2009, the size of the aggregate samples for feed materials shall be not less than the weight corresponding to 35 000 grains/seeds and the final sample shall be not less than the weight corresponding to 10 000 grains/seeds.

   The mass equivalent of 10 000 grains/seeds is provided in Table 1 below.

Table 1

Mass equivalent of 10 000 grains/seeds for different plants

Plant	Mass, in grams, corresponding to 10 000 grain/seed
Barley, Millet, Oat, Rice, Rye, Wheat	400
Maize	3 000
Soybean	2 000
Rape seed	40

ANNEX II

CRITERIA FOR SAMPLE PREPARATION AND METHODS OF ANALYSIS

In order to detect the presence in feed of the GM material referred to in Article 2, the official laboratories shall use the methods of analysis and control requirements described in this Annex.

A. PREPARATION OF SAMPLES FOR ANALYSIS

In addition to the requirements of Annex II Part A to Regulation (EC) No 152/2009, the following provisions shall apply.

1. **Treatment of the final samples**

Official laboratories shall use the standard EN ISO 24276, ISO 21570, ISO 21569 and ISO 21571 that indicate strategies for the homogenisation of the final sample (also designated as the 'laboratory sample' in the ISO standards), the reduction of the final sample to the sample for analysis, the preparation of the test sample and the extraction and the analysis of target analyte.

2. **Size of the sample for analysis**

The sample for analysis shall be of a size which ensures the quantification of GM material at a presence corresponding to the MRPL with a statistical degree of confidence of 95 %.

B. APPLICATION OF METHODS OF ANALYSIS AND EXPRESSION OF THE RESULTS

By derogation from Part C of Annex II to Regulation (EC) No 152/2009, the following rules for the application of methods of analysis and expression of results shall apply.

1. **General conditions**

Official laboratories shall comply with the requirements of ISO 17025 and use quantitative methods of analysis that have been validated by the European Union Reference Laboratory in collaboration with the European Network of GMO Laboratories. They shall ensure that, considering the whole analytical method starting with the treatment of the laboratory sample of feed, they are in position to carry out the analysis at the level of 0,1 % related to mass fraction of GM material in feed with an adequate precision (relative repeatability standard deviation less than or equal to 25 %).

2. **Rules for interpretation of results**

To ensure a level of confidence of approximately 95 %, the outcome of the analysis shall be reported as x +/– *U* whereby x is the analytical result for one measured transformation event and *U* is the appropriate expanded measurement uncertainty.

U shall be specified by the official laboratory for the whole analytical method and confirmed as described in the guidance document on Measurement Uncertainty for GMO testing laboratories [1] developed by JRC.

A feed material, feed additive or, in the case of compound feed each of the feed material and feed additive of which it is composed shall be considered as non-compliant with Regulation (EC) No 1829/2003 when the analytical result (x) for one measured transformation event minus the expanded measurement uncertainty (*U*) equals or exceeds the level of 0,1 % related to mass fraction of GM material. When results are primarily expressed as GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes, they shall be translated into mass fraction in accordance with the information provided in each validation report of the EU-RL.

[1] http://www.irmm.jrc.be/html/reference_materials_catalogue/user_support/EUR22756EN.pdf

European Commission

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Abstract

Genetically modified organisms (GMOs) are officially defined in the European legislation as "organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination".

The application of this technology is strictly regulated, and the European Union (EU) has established an extensive legal framework on GMOs since the early 1990s. The entire corpus of EU legislation on GMOs has been amended between 2000 and 2003, leading to the creation of a whole updated EU legal framework on GMOs as of 2003.
A key objective of the EU legislation on GMOs is to protect human and animal health as well as the environment. A genetically modified organism (GMO) or a food or feed product derived from a GMO can only be placed on the EU market after it has been authorised, on the basis of a stringent EU procedure based on a scientific assessment of the risks to health and to the environment. The EU legislation on GMOs also aims at providing information to EU consumers through mandatory GM labeling of food and feed products containing, consisting of or produced from GMOs.

The GMO analysis plays a key role in the implementation of the EU legislation on GMOs, be it to ensure appropriate labeling of approved GMO products or to detect the possible presence of unapproved GMOs on the market.

The present report provides an overview of the key provisions of this extensive EU legislation on GMOs. It also includes copy of the key EU regulatory texts on GMOs.

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